ASTS
American Society of Transplant Surgeons

February 9, 2026

The Honorable Mehmet Oz, MD, MBA
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

RE: Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model (CMS-5544-P)

Dear Administrator Oz:

On behalf of the American Society of Transplant Surgeons (ASTS), I am pleased to have the opportunity to comment on the proposed changes to the Increasing Organ Transplant Access (IOTA) Model (the "Proposed Modifications" or the "Proposed Rule"). ASTS represents approximately 2,400 professionals dedicated to excellence in transplantation surgery. ASTS advances the art and science of transplant surgery through patient care, research, education, and advocacy.

ASTS supports many of the changes set forth in the Proposed Rule. ASTS supports elements of the proposed Model changes that would:

- Explicitly exempt Department of Veterans' Affairs (VA) medical facilities and Military treatment facilities (MTFs) from the IOTA Model for Performance Year (PYs) two through six (2-6).
- Raise the low-volume threshold from a minimum of 11 kidney transplants performed annually during each of the baseline years to a minimum of 15 kidney transplants performed annually during each of the baseline years.
- Exclude multi-organ transplants (MOT) from the composite graft survival rate exclusion and inclusion criteria, in recognition of the fact that MOT recipients form candidate cohorts distinct from isolated kidney candidates, face completely different perioperative and long-term challenges, and have outcomes that are not comparable to those of otherwise matched kidney-alone recipients. Please note that while CMMI is proposing to continue to include kidney/pancreas transplants in the composite graft survival metric, ASTS believes that the continued inclusion of these transplants in the metric has the potential to confound outcomes, place programs with busy pancreas transplant programs at a disadvantage to their peers performing few or no pancreas transplants, and to discourage Model participants from transplanting these patients. We feel that kidney/pancreas candidates should logically be excluded from Model along with other MOT recipients.
- Provide CMMI with additional flexibility to modify various provisions of IOTA for participants affected by Extreme and Uncontrollable Circumstances.

- Authorize termination of an IOTA participant from the IOTA Model for certain violations of OPTN and HHS rules. Please note that while the Proposed Rule would authorize termination if an IOTA participant has violated HHS regulation; or if the OPTN has determined that an IOTA participant has violated the OPTN *Management and Membership Policies*; or the OPTN's Membership and Standards Committee (MPSC) policies[i], we believe that this language is too broad and subject to interpretation. Rather, we agree that termination should be authorized if an IOTA participant is determined to be a Member Not in Good Standing by the OPTN Board of Directors or if CMS takes action to de-certify the IOTA participant.

- Modify the requirement to notify attributed patients of their inclusion in the IOTA Model by limiting this notification requirement to Medicare beneficiaries only and to provide participants flexibility in choosing the mechanism by which notification is provided.

- Authorize repayment of amounts due from IOTA participants 60 days after the penalty notice. We believe that penalty payment should not be required until at least 90-120 days from notification of a penalty. In any case, the deadline for penalty payment should align with the deadline for CMS to make bonus payments to IOTA participants that earn them. Furthermore, no penalty payment should be payable while an IOTA participant's appeal of the penalty determination is pending, and IOTA should have the ability to negotiate repayment schedules.

ASTS notes that the increased regulatory burden imposed on Model participants by the proposed changes would be a significant burden to the ongoing operational efforts of participants to evaluate and list candidates with organ failure, to transplant those patients and to care for those transplant recipients. We note that deceased donor transplant volumes have risen every year for over a decade due to intense effort throughout the transplant ecosystem. The IOTA Model and ASTS are aligned in our desire for maintaining the highest possible quality of care while transplanting more patients. As the IOTA Model adds regulatory burdens tangential to the Model's main goal of increasing transplant access, however, it risks impeding participants' ability to achieve those shared goals. The regulatory burdens imposed by the original IOTA Model, which would be dramatically increased if the proposed changes to IOTA are enacted, are at odds with the foundational goal of increasing transplant access.

Our concerns related to the administrative burden posed by the Proposed Rule and our other concerns regarding the potential adverse impact of certain provisions of the Proposed Rule's provisions are set forth below.

I. Transparency

ASTS strongly supports increasing the transparency of the transplant process. For this reason, we support provisions in the Proposed Rule that:

- Require that IOTA participants publicly post patient selection and living and deceased donor waitlist criteria;
- Require that IOTA participants review their publicly posted waitlist criteria annually to ensure that the information on the publicly accessible website is current and accurate; and

- Provide that each IOTA participant's waitlist criteria will be posted on the CMMI IOTA website.

A. Notification of Changes in Waitlist Status

We support the intent behind proposed new provisions that would require IOTA participants to notify its IOTA waitlisted patients who are Medicare beneficiaries when their waitlist status changes. However, we believe that this communication is so critical that any requirements applicable to the processes governing candidate listing status changes should apply to all transplant programs and to all waitlisted candidates and should not be selectively applicable only to Medicare candidates waitlisted at IOTA participants.

We believe that this unmet need is best addressed on a national basis by the OPTN, which has published a proposal mandating written notification of status changes within 10 days. ASTS has submitted comments with the OPTN expressing concerns regarding the sufficiency of the proposed OPTN notification process and has recommended a more robust and patient-centric process (see page 2). We recommend that candidate waiting list status change notification processes be implemented on a national basis through the OPTN processes currently in progress.

The OPTN and proposed IOTA processes for notifying candidates of changes in waitlist status differ in key respects: Under the Proposed Rule, for example, the notification would be more comprehensive and notifications could be provided using a broad range of delivery mechanisms, but would be provided only when a candidate becomes inactive (but not when the candidate becomes active again). By contrast, under the OPTN proposal, the notification would be provided via U.S mail and notification would be provided both when a candidate becomes inactive and when they become active again. Our proposed approach combines elements of both the Proposed Rule and the OPTN proposed policy but differs from both in a key respect: We believe that for the process to be truly patient-centered, a candidate whose waitlist status changes should be notified through a discussion with a transplant team member and documented in the candidate's medical record. In our view, this more patient-centered approach is likely to be far more effective than written notification of any kind, however delivered, assuming the candidate can be reached in a timely manner.

We note that the proposed Model revisions stipulate that the status-change notification would only be imposed if the OPTN proposal is not adopted for the community. However, the timeframe for adoption is unclear, and if the OPTN requirements are finalized after the IOTA status change requirements are adopted, IOTA participants will be subject to double jeopardy in that they will need to prepare for two (potentially very different) notification regimes. Even if the OPTN proposal is not adopted, the proposed IOTA status change requirements, if finalized, will be one more administrative burden imposed on participants that are not borne by nonparticipants. We therefore oppose the proposal to require notification of status change and instead favor a uniformly applied and vetted national approach for this issue.

B. Semi-Annual Individualized Notification of Declined Organs ("Organ Declination Requirement")

While we are committed to increasing the transparency of the transplantation process, we strongly oppose CMS' proposal to require IOTA participants to provide semi-annual individualized notifications to "eligible IOTA waitlist beneficiaries" who have been waitlisted for at least three years, detailing the number and reasons for organ declinations made on their behalf. This is well-intentioned but extremely problematic policy. This proposed transparency requirements reintroduces, and makes more burdensome, a flawed idea already considered and rejected based on extensive public comments filed in response to the initial IOTA proposed rule, which would have required similar reporting on a monthly basis. It is puzzling to us that the Proposed Rule reintroduces a reformulated proposal to institute a requirement that we, and many others in the community, vehemently opposed with the initial Model, and which CMMI agreed to remove from the Model after that feedback. The reasons for our opposition to this proposal are set forth in detail in our prior comments, a copy of which is attached and incorporated by reference.

While we recognize that the organ declination requirement set forth in the Proposed Rule is less onerous than that proposed previously, and while we strongly support improved transparency, we are deeply concerned that the revised organ declination requirement still has the potential to have a dramatic, adverse impact on patient care by diverting scarce resources to administrative functions and addressing unsubstantiated patient concerns. Even more importantly, the provision of this information to patients has the potential to be extremely misleading, resulting in waitlisted patients' making decisions that are inconsistent with their previously stated desires, their best interests, and the objectives of the IOTA Model.

Changes in kidney allocation policy that were implemented in 2021 to broaden distribution of deceased donor kidneys substantially increased the number of organ offers made to transplant programs by OPOs. One study focusing on the period immediately following implementation of a broader geographic organ sharing allocation system indicated that median offer volume was 70% higher under the broader organ sharing allocation system (195 vs. 115 offers[ii]/center/mo., P<0.001), even though median transplant volume was similar under both systems, suggesting that organ declines have increased substantially due to allocation system changes beyond the control of IOTA participants or any other individual transplant center.[iii]

The following chart reflects the number of deceased donor kidney offers declined by a diverse group of ten of the highest-volume DDKT programs in the nation. Under the Proposed Rule, all decisions to decline an organ would be required to be reported to the patients to whom an offer is made: [iv]

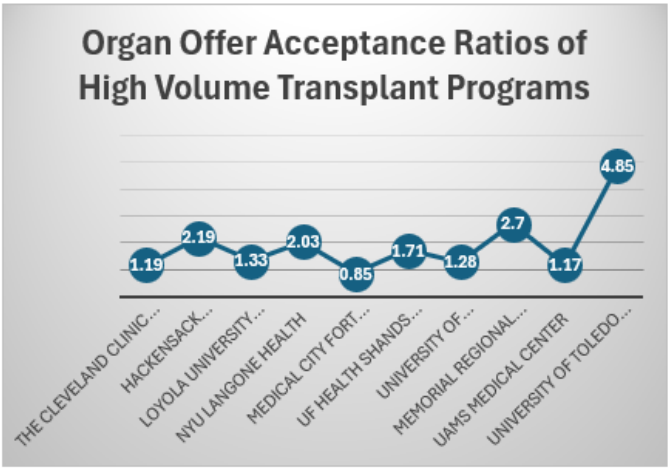
***The Cleveland Clinic Foundation**	22645
Hackensack University Medical Center	16300
Loyola University Medical Center	14885
***NYU Langone Health**	12493
***Medical City Fort Worth**	9788

UF Health Shands Hospital	9593
University of Cincinnati Medical Center	7993
Memorial Regional Hospital	6533
***UAMS Medical Center**	5732
University of Toledo Medical Center	633

**denotes IOTA participant*

While the number of organ offers declined may appear high, it is important to note that if a transplant program determines that an organ is not medically appropriate for transplantation, the organ is "declined" for all of the transplant program's waitlisted candidates who appear on the match run. For this reason, under the Proposed Rule, a transplant program's declination of a single organ offer may result in the need to notify multiple waitlisted candidates—sometimes over a hundred candidates for one organ decline. For example, consider a young donor with one severely injured kidney from a trauma that cannot be used safely in any patient, but that is offered to the entire national list. Under the Proposed Rule, notification of such an offer may be required to be sent to hundreds of patients at numerous transplant programs throughout the country.

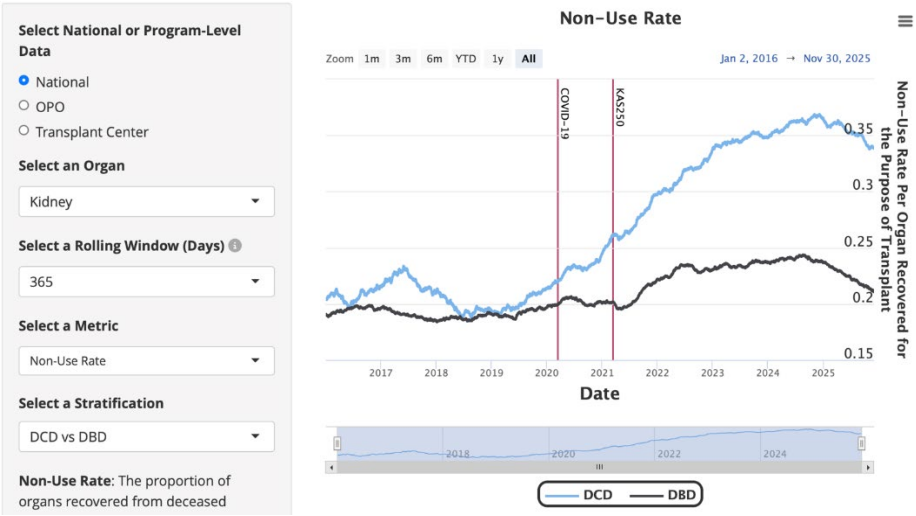
Confronted by numerous notifications of organs declined on his or her behalf, a candidate waitlisted at one of these high-volume centers may well conclude that she may have a shorter wait time if she were listed at a different transplant program that declines fewer offers; yet, these high volume transplant programs are all ranked at the top (five star) level when it comes to "getting a deceased donor transplant faster." Likewise, confronted by the notifications required under the Proposed Rule, a waitlisted candidate at one of these high-volume centers may well conclude that the candidate's transplant program is extremely selective about accepting organs; yet all these high-volume transplant programs except one have a "higher than expected" organ acceptance ratio. As illustrated by the chart below, there does not appear to be any relationship between the number of organ offers declined and a transplant program's offer acceptance ratio.



In short, taken out of context, the data required to be disclosed under the Proposed Rule may reasonably be expected to undermine waitlisted candidates' confidence in their transplant programs, to confuse waitlisted candidates about their transplant programs' organ acceptance practices, and to compromise their care.

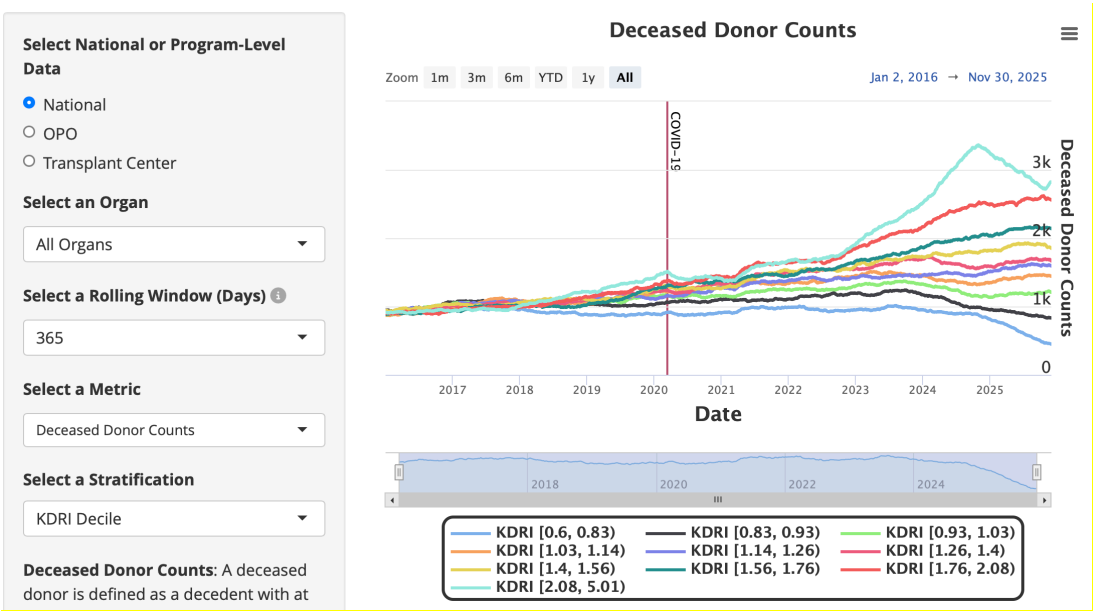
It is particularly problematic that the Proposed Rule would even require notification when an IOTA participant declines an organ, even if all the programs to which that organ is offered likewise find it unsuitable for transplant. As CMS pressure on OPOs to increase procurement and the number of organs procured for transplantation has risen, so has the number of organs declined by all transplant programs. The data suggests that this is because virtually all of the increase is attributable to procurement of lower quality organs whose transplantation may be highly problematic.

More specifically, the non-use of kidneys procured for transplantation has increased substantially over the past several years, coinciding with increased CMS pressure on OPOs and the implementation of broader organ sharing:



Altogether, of the 6,903 kidneys recovered but not transplanted in 2023, 4,967, or approximately 72%, were declined by all transplant programs, strongly suggesting that the organs involved were unsuitable for transplantation for any waitlisted patient.

A closer look confirms this conclusion: SRTR 2023 data indicates that a significant proportion of the increase in deceased donor organs procured by OPOs over the past several years are of extremely low quality, based on donor age, diabetes/hypertension history, cause of death, and other characteristics relevant to the relative risk of organ failure, as measured using Kidney Donor Risk Index (KDRI):



In the above chart, the turquoise line represents organs that have an estimated risk of failure that is two to five times that of the median and the red line represents organs that have an estimated risk of failure up to twice that of the median. Fundamentally, then, while OPOs are increasing the number of kidneys procured, the quality of a high proportion of these organs is extremely problematic, resulting in a substantial growth in the number of kidneys that are rejected by all programs.

As the result of these and other factors, for the most recent one-year period for which data is publicly available (July 1, 2024 - June 30, 2025), of the 1,897,338 deceased donor kidney offers made, only 19,856 were accepted, leaving approximately 1,877,482 organ offers declined. Assuming that approximately 60% of these declinations were for Medicare patients waitlisted at IOTA facilities, and that 35% of these waitlisted Medicare patients had been on the waitlist for three years or more, the organ declination requirement would have required IOTA participants to provide approximately 200,000 organ declination notifications had it been in effect in 2024 - 2025.[v] Clearly, the Proposed Rule would impose an extraordinary burden on IOTA participants—a burden that would reduce the time and resources that transplant teams would have available to provide patient care.

In short, considering the significantly increased number of organ offers received by IOTA participants in recent years and the decreased quality of the organs procured, even the scaled down organ declination requirement in the Proposed Rule would impose an extraordinary administrative burden on IOTA participants, diverting substantial resources from patient care. Moreover, and equally importantly, ubiquitous patient notification of offers for organs unsuitable for transplantation likely would significantly undermine waitlisted patients' confidence in the organ procurement system as a whole. Nothing is to be gained, and much may be lost by further erosion of public trust in the transplant system.

The regulatory impact statement significantly underestimates this burden. Specifically, the regulatory impact statement estimates that the total cost of reviewing a transplant program's waitlist criteria with a patient twice a year; informing patients of changes in their waitlist status; and providing semi-annual reports to waitlisted Medicare beneficiaries of the number of organs declined on their behalf is $9,519 per year. This estimate grossly understates the resources that would be diverted from patient care if the Proposed Rule is finalized in its current form.

Currently available data sets concerning organ offer declines give very basic information that cannot detail why an organ was *truly* not acceptable for that candidate. To have the information necessary to explain the data in plain language, as required by the Proposed Rule, the transplant center would need to have a transplant surgeon or nephrologist look up each organ offer in UNET to gather the actual details as to why that offer was declined. This can easily be over 100 declines per candidate per year. The time it would take to do this is easily over four hours per patient and the task would need to be performed in most transplant programs by a transplant surgeon (in some programs by a transplant nephrologist) but not by a nurse practitioner, as the impact analysis assumes due to the need to review the actual donor and organ information to develop a detailed reason for offer decline.

In fact, fulfilling the requirements related to offer declinations would require substantial system changes, since this kind of individualized data is not available from any public source. Obtaining this data on an individualized basis would take many weeks to accomplish and most certainly could not be provided to waitlisted patients on the timetable suggested by CMS (i.e. provision of individualized data within the first month after the close of each six-month period.) Unless and until data systems are configured to provide this type of individualized data on a real-time basis, requiring transplant programs to provide individualized data to patients would impose extraordinary administrative costs on IOTA participants.

Perhaps most importantly, the regulatory impact analysis completely fails to consider the time and resources necessary to answer patient inquiries regarding the data that they are provided. It is possible, if not likely, that many, if not most, patients receiving the information referenced in the Proposed Rule will want to discuss declined offers in greater detail with the transplant team, potentially requesting in depth explanations regarding the reasons behind each decision. The time that transplant surgeons and nephrologists would need to divert from patient care activities is virtually incalculable. Transplant programs, already under financial pressure, have neither the resources nor the personnel to have these conversations with waitlisted patients without diverting time and attention from transplanting patients. To require scarce resources to be expended in this manner is inconsistent with what we understand to be the primary purpose of IOTA—to increase access to transplantation.

We also believe that the elements to be included in the semi-annual reports that would be required by the Proposed Rule have the potential to mislead patients. For example, the Proposed Rule would require IOTA participants to include in their reports whether each declined kidney was transplanted into another patient, which may well suggest to the patient that it was inappropriate for the IOTA participant to decline the organ on that patient's behalf. But an organ that is clinically appropriate for one patient may not be clinically appropriate for another, and not all transplant

programs are equally equipped to perform transplants of hard-to-place organs. It is unclear to us how providing this information to waitlisted Medicare beneficiaries would further the basic objective of the demonstration—to improve transplant access. On the contrary, such data has the potential to significantly undermine waitlisted patients' trust in the IOTA participant and in the transplant system in general.

We believe that some of the alternatives considered by CMS have the potential to reduce the administrative burden that would be imposed if the Proposed Rule were finalized without change. For example, since the proportion of deceased donor kidneys declined by all transplant programs has grown to nearly 30%, excluding these universally declined organs from the notification requirement would substantially reduce the administrative burden involved and relieve IOTA participants of the responsibility of explaining the reasons for OPO procurement of organs unsuitable for transplantation for any purpose. Revising the regulation from "opt out" to "opt in" also has the potential to reduce the administrative burden without limiting the options of those waitlisted patients interested in obtaining the data. In addition, the idea of excluding from the notification those deceased donor kidneys that were accepted only after having been offered and declined by a significant number of programs may warrant further consideration. The Proposed Rule indicates that that HRSA is planning to make detailed declined organ data available in public reports, and if this is done, there would be no need for CMS to impose additional burdens on IOTA participants. Since the proposed organ declination requirement would not go into effect until performance year three, we urge CMS to explore all these alternatives further.

Also, we strongly urge CMS to consider substituting other mechanisms for increasing transplant program transparency with respect to their organ acceptance practices. These may include, for example:

- Requiring participating programs to discuss their organ acceptance practices with waitlisted patients at the time of listing and annually thereafter, and to document those discussions.
- Making the transplant program's organ acceptance ratio data available to waitlisted patients, as recommended by our initial comments.
- Requiring participating programs to review with the patient the data provided via the SRTR Kidney Transplant Decision Aid and his or her projected waiting list time, as calculated based on the tool set forth on the SRTR Kidney Transplant Waiting Times website at the time of listing, and provide instructions to the patient regarding how to use these tools.

We recognize that some patients and patient organizations have indicated that individual patients would like to have information on organs declined on their behalf. We respectfully suggest that the question is not so simple. No new mandate on transplant programs comes without cost. The question is not whether waitlisted patients would like to have detailed information on organs declined on their behalf, but rather whether they would prefer that transplant surgeons spend their time explaining why an organ (which may have been universally rejected as unsuitable for transplantation) was declined in their particular case, or to have that surgeon spend his or her time transplanting patients, conducting evaluations of transplant candidates, or providing post-transplant care. To put it simply, finalizing the Proposed Rule in its current form will undermine IOTA participants' ability to achieve the increased transplant access that is the primary goal of the IOTA model, while adversely impacting patient care.

C. Semi-Annual Review of Candidate's Organ Acceptance Preferences

ASTS understands and agrees with increasing transplant candidates' understanding of, and involvement in, their care, and we support transplant candidates' giving serious consideration—and reconsideration—to the type of organs they will accept. The Proposed Rule clarifies that, every six months, IOTA participants are required to review with IOTA-eligible beneficiaries "transplant organ offer acceptance criteria", which the Proposed Rule defines as, "individualized patient acceptance parameters that kidney waitlist patients…may elect regarding the categories of organ offers they are prepared to accept for transplantation." We believe that the language should be clarified to specify that the "categories" referred to in this new regulatory definition are those that are recognized for organ matching purposes in DonorNet (e.g. Expanded Criteria Donors or donors with KDPI exceeding 80%). We also continue to believe that it is not necessary—and may be unnecessarily distressing—for candidates to be queried every six months regarding the organs that they are willing to accept and that such communications should not take place more frequently than annually.

II. Proposed Modifications of Graft Survival Metric

CMMI is proposing two interrelated changes to the graft survival metric: First, the Proposed Rule would apply a new and untested risk adjustment methodology to determine participants' graft survival scores. Second, the Proposed Rule would modify the scoring methodology in a manner that would make it more difficult for participants to earn points.

While ASTS strongly believes that it is critical to apply a risk adjustment methodology in applying the graft survival metric, we oppose the methodology set forth in the Proposed Rule. On its face, it appears clear that the proposed risk adjustment methodology was formulated without sufficient clinical input. For example, under the Proposed Rule, risk adjustment for both donors and recipients are based on, among other things, "Plasma renin activity (PRA) levels." However:

- "PRA" does not stand for "Plasma renin activity", but rather "Panel Reactive Antibody."
- PRA is no longer used and has been replaced by an updated measure, cPRA (calculated Panel Reactive Antibody).
- cPRA is not evaluated for donors, only for recipients.

In addition, the proposed risk adjustment methodology for both donors and recipients include consideration of "kidney function (eGFR/creatinine)". Estimated GFR in the candidate is not useful once they are on dialysis, which most are. This value only reflects the clearance of the dialysis treatment, not their native kidneys. Given the increased complexity of many donor situations, eGFR is also problematic for donors—more so today than in the past. For example, a potential donor may be in acute renal failure and on dialysis themselves, with their measured serum creatinine and therefore estimated GFR very good, but purely artificial due to the function of the dialysis machine. This is not accounted for in the KDPI and would very falsely characterize these donated kidneys if they were used.

It is clear that the proposed risk adjustment methodology was formulated without robust and comprehensive input from experts in the field. Developing risk adjustment is difficult as well as dynamic. Considering the clinical expertise required and the need for continuing refinement, the regulatory process is an inappropriate vehicle for the formulation of risk adjustment methodologies. Any methodology derived through the regulatory process necessarily must be rudimentary.

In the context of the IOTA Model, if risk-adjustment is not robustly modeled and monitored for accuracy, it is potentially worse than no risk-adjustment at all. A risk adjustment methodology that is rudimentary is likely to be easily manipulated: patient and donor selection may become "gameable" by participants to the detriment of both patients and transplant programs that refrain from manipulation.

A better approach, and one recommended by ASTS in our comments on the IOTA Model as initially proposed, is to adopt the SRTR risk-adjustment model. This is aligned with other provisions of the IOTA Model that already incorporate SRTR calculations in determining the Organ Offer Acceptance Rate ratio. Use of SRTR risk adjustment methodologies to determine performance on the graft survival metric is a logical extension of the same risk adjustment methodology in assessing participants' organ acceptance.

The Proposed Rule suggests that the SRTR risk-adjustment system may lead to risk-aversion in clinical decision-making. We believe this is a baseless argument: a system that does not include any risk adjustment has the potential to result in the greatest increase in risk aversion. The better a risk-adjustment model fits actual risks, the less impact it will have on clinical decision-making. The proposed risk-adjustment system is extraordinarily simplistic and will adjust risk in ways that are wildly disparate from the actual risks associated with donor and recipient pairing; the more simplistic the risk adjustment model, the greater the potential for manipulation. This simplicity places IOTA participants in jeopardy of an outcomes regime unhinged from actual risks, puts patients at risk of receiving transplants within the Model that are acceptably risky by CMMI's crude risk adjustment regime but extremely high-risk in the real world, and has the potential to foreclose transplant options for candidates for which the poorly designed risk adjustment model incorrectly predicts excessive risk.

ASTS believes that risk adjustment is critically important but extraordinarily complex. To be trustworthy, the process necessarily must be dynamic and difficult to "game." For the reasons set forth in our prior comments, we strongly urge CMS to utilize SRTR risk adjustment models in determining participants' performance on the graft survival metric.

Without the adoption of a reasonably reliable risk adjustment methodology, the graft survival metric has the potential to severely penalize those transplant programs that transplant sicker patients or those that accept lower quality organs. It was based on these concerns that CMMI finalized the current scoring system on the graft survival metric.

In addition, we support continuing the Graft Survival Rate Scoring as in the 2024 Final Rule (Table 5) and disagree with changing to the proposed Table 6. The greater number of outcome categories

and a minimal point earning for any transplant is more aligned with the intent of this CMMI project, to increase the number of transplants performed in this country.

Finally, the Proposed Rule solicits public comment on other changes that might be considered in assessing the quality of care provided by participants. We remain concerned that determining one fifth of a participant's final score on transplant outcomes, measured over a cumulative six-year period, has the potential to increase rather than decrease risk aversion among program participants. ASTS would be pleased to work with CMMI to formulate quality measures that are less likely to interfere with the primary objective of IOTA: increasing access to transplantation.

III. The Inclusion of Medicare Advantage (MA) Enrollees in Determining Financial Incentives

The Proposed Rule solicits comments on whether to include MA enrollees in determining financial incentives for demonstration participants. In its prior comments, ASTS strongly urged CMMI to include MA enrollees in determining financial incentives under the IOTA Model, and the reasons for including them has become stronger since that time: according to USRDS data, the shift away from Medicare FFS to MA continued in 2023. For the second year, more than half of Medicare beneficiaries starting treatment for ESRD were covered through MA, and almost half of Medicare beneficiaries with *established* ESRD had MA coverage.[vi] As the Proposed Rule itself observes, MA is projected to eclipse 60 percent penetration during the Model testing period. Under these circumstances, providing incentives only for the transplantation of Medicare FFS beneficiaries simply makes no sense, if the objective of IOTA is to increase access to transplantation for Medicare beneficiaries overall.

However, we strongly object to reducing the maximum payment incentive from $15,000 to $10,000 if Medicare Advantage enrollees become eligible for incentive payments after transplantation. Medicare saves money whenever a Medicare beneficiary is transplanted—regardless of whether the beneficiary is enrolled in Medicare Advantage. In fact, the regulatory impact statement accompanying the Proposed Rule indicates that Medicare savings are $5,000 higher when an ESRD-eligible Medicare Advantage enrollee is transplanted than when an ESRD-eligible Medicare FFS is transplanted, due to the idiosyncrasies of Medicare's methodology for determining Medicare Advantage capitated payments to MA plans. Under these circumstances, if anything, the maximum payment incentive should be increased as the result of inclusion of MA enrollees in incentive payment calculations.

IV. Responses to RFIs related to waitlist access and allocation out of sequence

The Proposed Notice also solicits public comment on two additional questions:

- Whether to include a pre-transplant process or outcomes measure to evaluate access to a participant's waitlist
- How to appropriately handle allocation out of sequence (AOOS) for IOTA participants

The Secretary, through the Health Resources and Services Administration (HRSA), is launching a data initiative to address waitlist access and the OPTN, under HRSA's oversight, is seeking to address the complex issues involved in the spike in AOOS. ASTS' positions with respect to both issues are publicly available:

- ASTS comments on pre-waitlist data collection
- Ethical Considerations in the Allocation Out-Of-Sequence Deceased-Donor Organs
- ASTS Analysis of Out of Sequence Allocation of Donor Organs for Transplant

ASTS strongly believes that it would be a serious error to add additional process or outcomes measures to evaluate access to a participant's waitlist or to deter AOOS. Both issues are already the focus of diligent efforts by the OPTN and HRSA. Imposing additional (and potentially duplicative or conflicting) requirements on IOTA participants has the potential to significantly complicate the establishment and implementation of a national approach; disadvantage IOTA participants relative to their peers that are not participants; and to damage the Model. Moreover, we believe that it is critical to ensure that IOTA remains focused on its overarching objective—to increase kidney transplant access. The more complex the Model becomes, and the more secondary objectives are pursued, the less likely it is that the demonstration will yield actionable insight into question of whether, and how, access to kidney transplantation can be increased.

We appreciate the opportunity to comment on this important Proposed Rule and look forward to continued dialogue with CMMI regarding refinement of the IOTA Model. If you have any questions regarding these comments, please contact ASTS' Director, Advocacy & Professional Practices, Emily Besser, at Emily.Besser@asts.org.

Respectfully,

James F. Markmann, MD, PhD

[i] The Proposed Rule refers to the MPSC as the "Management and Membership" committee.
[ii] This study measured the median number of deceased donors offered per center per month—meaning one donor offered to three candidates at a center would be counted as a single donor offer to that center. Therefore, this data understates the burden that would be imposed by the Proposed Rule, which may require that a single declined organ be reported to multiple waitlisted patients.
[iii] https://pmc.ncbi.nlm.nih.gov/articles/PMC10527286/pdf/nihms-1909172.pdf.
[iv] Computed as the number of organ offers minus the number of organ acceptances in 2023.
[v] Based on data included in the PSRs for this period, and the assumption that 60% of waitlisted patients at the IOTA participants are Medicare patients.
[vi] https://usrds-adr.niddk.nih.gov/2025/introduction

July 12, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Submitted Electronically

Re: [CMS-5535-P]; RIN 0938-AU51; Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model (IOTA Model Proposed Rule)

Dear Administrator Brooks-LaSure:

I am writing on behalf of the American Society of Transplant Surgeons (ASTS) in response to the IOTA Model Proposed Rule. 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.

Over the past several years, ASTS has engaged in extensive discussions with the Centers for Medicare and Medicaid Innovation (CMMI) regarding the potential for a voluntary demonstration model to increase the availability of kidney transplantation for Medicare beneficiaries and other patients with End Stage Renal Disease (ESRD). The IOTA Model appears intended to pursue the same objective and incorporates many features of our proposal. We are appreciative of CMS' recognition of the importance of increasing access to renal transplantation for Medicare and other patients for whom it is clinically appropriate and recognize the time and effort that CMMI has dedicated to designing the IOTA Model. After thorough review, we regret that we cannot support the implementation of the IOTA Model as proposed. Our recommendations for modifications to the proposed Model that would address those concerns are detailed below.

Our five major concerns relate to the IOTA Model's inaccurate estimate

estimate of cost savings attributable to transplantation relative to continued dialysis, transplant volume metric, the transparency requirements, the outcomes measures, and the Model's insufficient focus on increasing living donor transplant volumes:

- The estimated cost savings attributed in the Model to transplantation relative to dialysis appear to grossly underestimate the economic benefits that accrue from transplantation. As this input is a critical component of the formula utilized in developing the financial incentives achievable within the model, this gross underestimation of the cost savings achieved by transplantation relative to dialysis leads to incongruously low achievable economic incentives for high performing participants within the Model.

- The proposed volume targets are fundamentally flawed. These targets penalize currently high performing programs and seem designed to punish participating transplant programs for increasing transplant volumes which will be required to increase transplant volumes more significantly to avoid penalties and are likely to result in significant penalties on the many transplant programs that fall below target performance. This structure may inhibit, rather than encourage, growth in transplant access and volume.

- The requirement that participants provide monthly reports to individual waitlisted patients regarding the number of organs offered to them and declined, and the reason for those declines would require extraordinary administrative resources to implement. While we agree that transplant programs should provide more transparency with respect to their organ acceptance practices, the transparency requirements in the proposed IOTA Model are untenable for transplant programs, are not likely to provide waitlisted candidates actionable information, and are unlikely to spur transplant programs to increase acceptance of hard-to-place organs. Essentially, the proposed reporting requirement will place an unmanageable burden on participants

- The IOTA Model proposed outcome requirements, which hold participating transplant programs responsible for graft survival for six years post-transplant, this measure is not risk-adjusted. In addition, these requirements fail to recognize the realities of post-transplant care, which is provided mostly by community nephrologists and other members of community-based care teams. Critically, no database currently traces post-transplant outcomes for six years, and requiring participating programs to establish systems to perform this function would impose on them an extraordinary unfunded mandate and divert resources from the primary mission of increasing transplant volume. The monitoring of kidney recipients to track graft survival for a period of six years imposes an enormous new unfunded mandate that collectively dwarf the

potential financial incentives for high-performing participants, and thereby work in direct opposition to the fundamental goal of increasing transplant volume.

- The benefits of living donor kidney transplantation relative to deceased donor transplantation are abundantly clear for patients, and the economic advantages for payers are equally clear. As proposed, the Model does an insufficient job of incentivizing living donor transplantation.

We firmly believe that, at a minimum, these five elements of the proposed IOTA Model should be modified or eliminated if the IOTA Model is to achieve its primary objective.

I. Overall Structure and Objectives

As recognized by the IOTA Proposed Rule, and as supported by extensive data that need not be repeated here, transplantation is the best treatment option for many patients with ESRD and the most cost-effective treatment for payers, including the Medicare Program, which provides primary or secondary coverage for a large majority of the prevalent ESRD patient population. Given the manifest clinical and financial advantages of renal transplantation relative to all other forms of renal replacement therapy, the demonstration model advanced by ASTS in its discussions with CMMI focused on a single clear but aspirational objective: To increase the number of transplants performed by the Nation's renal transplant programs while maintaining excellent clinical outcomes. In accordance with this strategic objective, we proposed a model design that was relatively simple, based on the number of transplants performed by each program during the demonstration period relative to the average number performed during a historical baseline period.

By contrast, while the primary metric utilized in determining performance under the IOTA Model is based on the number of deceased and living donor transplants performed by a participating transplant program, the IOTA Model also considers myriad other factors related to efficiency, quality, outcomes, transparency, disparities, patient decision making, data reporting and other factors. These additional items, most of which are only tenuously linked to the primary goal of increasing transplant volume and many of which are outside the direct control or scope of transplant hospitals, unnecessarily complicate the demonstration Model and are reasonably likely to render it ineffective in advancing its fundamental objective of increasing transplant volumes.

In fact, we are concerned that, as currently structured, the IOTA Model is highly likely to result in significant financial penalties for a large number of renal transplant programs, thereby potentially reducing both quality and access to renal transplantation for the Nation's ESRD patient population, while imposing additional administrative burden on, and disruption for, transplant programs that are already facing substantial pressure on margins due to macroeconomic factors beyond their direct control and an uncertain regulatory environment related to the HRSA OPTN Modernization initiative.

Recommendation: We urge CMS to significantly simplify the IOTA Model to focus more narrowly on increasing access to renal transplantation.

The pressures on transplant programs in today's regulatory and macroeconomic environment cannot be overstated. Transplant programs are among the only providers subject to public one-year outcomes requirements and the level of performance expected by payers and the public is constantly increasing: Transplant programs with two or three star SRTR ratings and programs failing to meet strict OPTN transplant performance measures face exclusion from in-network commercial payer status and potential financial ruin. At the same time, the implementation of new organ allocation methodologies has disrupted longstanding working relationships between transplant programs and their local Organ Procurement Organizations (OPOs), while requiring the institution of new, and costly, processes to screen the extraordinary increase in organ offers resulting from the allocation of organs over broader geographic areas. The new allocation methodologies have likewise resulted in significant increases in transplantation costs and technological changes, including new perfusion technologies that place increased cost pressure on transplant program budgets. Additionally, the transplant community must anticipate substantial changes resulting from the OPTN Modernization Initiative and from de-certification of underperforming OPOs under CMS' new certification regulations, both of which will unfold during the IOTA Model demonstration period and both of which will impact transplant program performance and costs.

Macroeconomic pressures stemming from the COVID-19 pandemic, primarily ongoing irremediable staffing shortages with attendant disruption of hospital operations and massive increases in staffing (nursing and ancillary staff) costs have put incredible pressure on kidney transplant service lines, which have always been a low-margin contributor at best to hospital finances. Inflationary pressures have not been kind to health care supply chains, putting further strain on the ability of hospital systems to maintain, much less expand, kidney transplant volumes. CMS has had a gratifying and deeply appreciated degree of insight on these issues over the past few years. CMS has eloquently expressed an understanding that regulatory overreach with the invariably associated unfunded mandates accompanying that provide powerful disincentives for the risk-taking and investment needed to systematically increase the listing of higher risk candidates and utilization of higher risk donor organs. It is therefore concerning to find that the well-intentioned IOTA Model would create a gauntlet of unfunded mandates whose costs will easily exceed even the most optimistic financial rewards possible in the proposed Model. This is not the way forward.

Recommendation: **We urge CMS to eliminate or mitigate the proposed penalties and to eliminate or modify those requirements that impose significant unfunded mandates on participating transplant programs.**

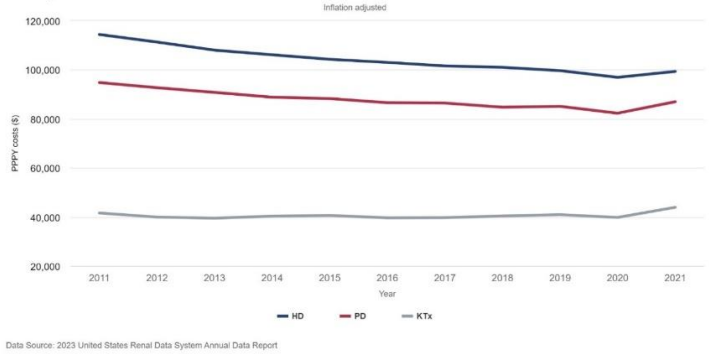
Recent regulatory changes, and the transplant community's response to those changes, have resulted in significant operational changes in organ allocation and organ offers. In response to intense pressure to improve performance in organ procurement and transplantation of procured organs, the willingness of OPOs to procure and offer even more marginal organs continues to increase, contributing to increasing organ non-use (as the number of non-transplantable organs offered nationwide increases). In addition, this pressure has resulted in a sharp increase in out-of-sequence organ placement: In fact, at this stage, we understand that nearly 20% of deceased donor organs—most of which are deceased donor kidneys—are placed out of sequence. These organs—not all of which would be considered organs at risk of discard under accepted clinical standards—are generally directed to higher volume centers located in urban areas. To the extent that the quality of organs offered for transplantation and patterns of organ offers are changing, it is inappropriate to determine baseline targets based on historical performance, without adjusting for these evolving trends.

> **Recommendation**: **With the extraordinary regulatory, technological and allocation changes impacting transplantation at this time, we urge CMS to postpone implementation of the IOTA Model until the impact of recent changes in organ offer patterns can be assessed and appropriate adjustments to target volumes can be built into the Model.**

We believe that one of the IOTA Model's structural deficiencies is directly related to a significant underestimation of the ten- year savings that may result from increased transplant volumes used in calculating the financial incentives for high-performers in the Model. The Regulatory Impact statement accompanying the IOTA Model Proposed Rule estimates that renal transplantation results in approximately $40,000 in Medicare savings per beneficiary transplanted over a 10- year period. We believe that this estimate is in error and substantially understates Medicare savings that may result from increased transplantation.

Data from the 2023 USRDS Annual Data Report demonstrates an inflation adjusted difference in Medicare FFS spending for beneficiaries with ESRD of roughly $70,000/person/year.

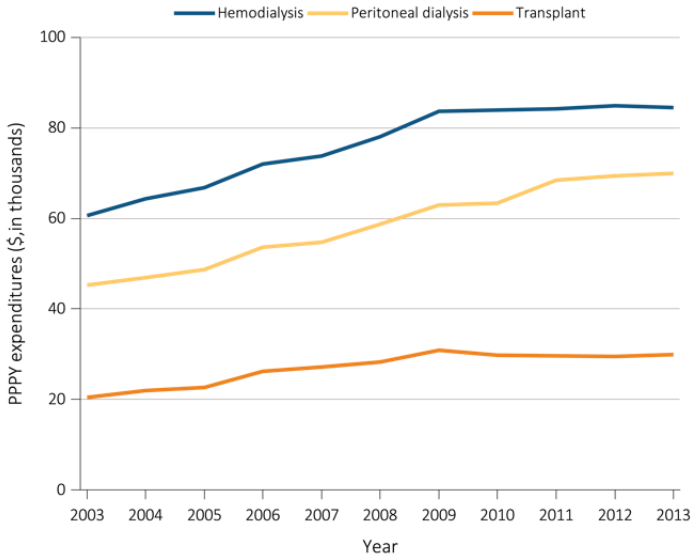
Figure 9.11 Per person per year Medicare fee-for-service spending for beneficiaries with ESRD, by treatment modality, 2011-2021



Data Source: 2023 United States Renal Data System Annual Data Report

Studies in the peer-reviewed literature by Schnitzler et al[1] and by Gill et al[2] are concordant with the USRDS data above, with estimated cost savings attributable to transplant versus dialysis of roughly $60,000 per person per year. The study in the peer-reviewed literature that provides an estimated cost-savings per patient closest to that incorporated in the IOTA Model is by Axelrod et al[3]. That study assumed a monthly cost of dialysis of only $3,639, which does not correlate with the cost estimates in the data cited by that study. We have attached Figure 11.7 from the 2015 USRDS Annual Report, which covered the period studied in the Axelrod paper and was cited in the Axelrod paper. As noted in the figure, the cost savings of transplant relative to hemodialysis are roughly $50,000 per person per year. The weighted cost differential (hemodialysis is more prevalent than peritoneal dialysis) is approximately $44,000 per person per year (utilizing prevalence figures of dialysis modalities from this epoch).

Figure 11.7 Total Medicare ESRD expenditures per person per year, by modality



Data Source: Reference Table K.7,K.8,K.9. Period prevalent ESRD patients; patients with Medicare as secondary payer are excluded. Abbreviations: ESRD, end-stage renal disease.

Additionally, the Axelrod study did not include the costs of death on the waiting list (approximately $65,000/patient). More importantly, that study provides an estimated 10-year average cost of dialysis of $292,000, which is not concordant with the data (average cost was approximately $830,000/10-years for hemodialysis in this epoch and $440,000 for a weighted average of hemodialysis or peritoneal dialysis). CMMI admits that the

[1] https://www.amjtransplant.org/article/S1600-6135(22)08010-8/fulltext
[2] https://www.amjtransplant.org/article/S1600-6135(22)09730-1/fulltext
[3] https://www.amjtransplant.org/article/S1600-6135(22)09535-1/fulltext

Axelrod study was a key data source for the IOTA Model inputs (personal communication with T. Duvall, June 2024), but the study in question should not be used as a primary source of data for informing the IOTA Model inputs or generating the IOTA Model financial incentives. The evidence clearly points to the Axelrod study results being an outlier and not a suitable source upon which to base Model construction.

Since CMMI demonstration projects, including the IOTA Model, are required to result in program savings, this significant underestimation of the potential savings of increasing transplantation significantly impacts the IOTA Model design, which must limit the thresholds for attaining, and quantitative amounts afforded high performers to meet budgetary targets. In fact, the budgetary constraints resulting from underestimating transplant savings inherent to the proposed Model may make net positive incentives extremely difficult, if not impossible, to achieve.

> **Recommendation**: **We urge CMS to work with the Office of Management and Budget to review the estimated savings resulting from transplantation to be consistent with those provided by USRDS and the relevant clinical literature. We further urge CMS to revise the potential financial incentives of the model upward in congruence with the more accurate estimate of the per person, per year cost benefit of transplantation relative to maintenance dialysis.**

We are also concerned that the IOTA Model requires mandatory participation by transplant programs located in half of the Nation's DSAs. While we understand that a mandatory model eliminates the self-selection biases that may result from a voluntary model, we believe that a voluntary study that is designed to solicit participation of transplant centers representative of the field would yield valuable data with which to evaluate the potential impact of financial incentives on transplantation rates while minimizing disruption for transplant programs whose regulatory environment is already in the midst of extraordinary upheaval.

> **Recommendation: We urge CMS to consider whether the necessary data regarding the impact of financial incentives on transplant volume could be obtained through a smaller targeted voluntary model.**

II. Eligibility

The IOTA Model would exempt transplant programs that did not perform 11 or more transplants for patients aged 18 years or older annually, regardless of payer type, during each of the baseline years.

> **Recommendation: ASTS supports the "small transplant program" exemption criteria set forth in the proposed IOTA Model.**

III. The Kidney Transplant Volume Metric

Under the IOTA Proposed Rule, sixty percent (60%) of the points (up to 60 points) will be based on kidney transplant volume (living and deceased) during each performance year relative to historic baselines. More specifically, under the Model, a "baseline" will be assigned to each participating transplant program based on that transplant program's living and deceased kidney transplant volume over a three-year historical period. Each transplant program's baseline will be determined by the highest number of living donor transplants performed during any of the three years and the highest number of deceased donor transplants performed during any of the three years. The transplant program's "target" volume for each of the six performance years will be determined based on the national average increase in living and deceased donor transplants for the year two years prior to the performance year. Based on recent historical data, CMS estimates that baseline rate of national transplant volume growth at approximately 6-7% per annum.

- Determining each transplant program's historical baseline by adding the highest number of living donor transplants performed during any of the three years and the highest number of deceased donor transplants performed during any of the three years sets transplant programs up for failure. The IOTA Proposed Model states that formula for determining each transplant program's historical baseline is proposed because it most accurately reflects each transplant program's volume "capacity." However, a transplant program's annual transplant volume is necessarily limited by whether, and where, its waitlisted patients appear on the OPTN match run(s) during that year and whether the organ ultimately offered to any individual patient is clinically appropriate for transplantation into that patient—i.e., by factors beyond the transplant program's control and independent of its "capacity." Moreover, annual volume may vary significantly from year to year, making it difficult to utilize any individual year's volume as a guide to future performance, especially for smaller programs and those in more remote areas.

- The stated goal of the IOTA Model is to increase transplant volumes sustainably and substantially. This goal should be aspirational, yet achievable, for participating programs. Perusal of center-specific national transplant data reveals incredible year-to-year variability in volumes, particularly for living donor programs. Many programs have a 50% difference between the highest and lowest volume year over just a three-year period. That is dramatic evidence of the inadvisability of using the peak volume over the historic cohort period as a baseline metric.

  Recommendation: We recommend that CMS use the arithmetic mean of living donor and arithmetic mean of deceased donor transplants performed by each participating center over a historical period of at least 3, but ideally 5, years to establish that participating programs volume baseline.

- Not only does the IOTA Model program design utilize a transplant volume baseline that will be difficult for transplant programs to replicate (let alone exceed), but it also trends that baseline forward, such that the more a participating transplant program increases its volume, the greater its challenge for the following year. Again, the IOTA Model sets participating transplant up for failure by building into the model design a baseline expectation of increased transplant volumes, failing to recognize that transplant volumes typically vary from year to year based on a myriad of factors that are beyond the control of the transplant program.

  Recommendation: The IOTA Model design should be modified to determine the baseline based on the average number of transplants performed during a fixed historical period, to ensure that participating transplant programs are not penalized for their success in increasing transplant volumes.

  The proposed formula for determining a transplant program's target assumes that each participating transplant program should be able to increase the number of transplants it performs by the national growth rate for at, the national average, an annual increase that historically has been in the range of 6-7% per year, according to the IOTA Model Regulatory Impact Statement. If the national average continues to grow at this rate, by the sixth year of the demonstration a transplant program would have to increase the number of transplants it performs by at least 140% of best historical performance in order to earn 30 out of the 60 available transplant volume points, which likely would leave them without having earned any incentive payment for the year.

- Notably, the target volume formula proposed in the IOTA Model penalizes precisely those transplant programs that have best mobilized to meet the Nation's need for increased access to renal transplantation—the highest volume transplant centers. In order to increase the number of transplants it performs by 6-7% per year a high-volume transplant center obviously needs to perform a significant greater number of transplants than a low volume center and with each passing demonstration year, a high volume center is increasingly likely to be penalized, even if the number of transplants it performs far exceeds its performance during the base period. If participating transplant programs respond to the incentives, the national average growth rate will increase during the period of the demonstration, with the result that, for each year of the demonstration project, targets will become more and more difficult to meet. Again, the model design penalizes transplant programs for responding to the Model's incentives. Using the ongoing national transplant volume to establish new volumes for the 50% of the nation's transplant programs serving as participants while those participants are performing over half the nation's transplants (because small programs are excluded from participation) is mathematically inconsistent and philosophically disingenuous.

The extraordinary pressure that the IOTA Proposed Model places on participating transplant programs to increase kidney transplant volumes, raises concern that transplant programs may be unlikely to put in place or to maintain organ offer "screens" that are necessary to improve the organ matching system efficiency. Over the past several years, the OPTN has worked hard to convince transplant programs to put in place these "screens" which enable the organ matching system to bypass transplant programs that are unlikely to accept specific organ offers, thereby improving system efficiency and reducing cold ischemic time for deceased donor kidney offers.

IV. Efficiency Measure

Under the Proposed IOTA Model, 20% of a participating transplant program's score will be based on its offer acceptance ratio, as computed using the current SRTR methodology. However, the IOTA Model would establish performance thresholds and targets considerably more stringent than those used by the MPSC to "flag" underperforming transplant programs.

While ASTS is dedicated to reducing the number of transplantable organs that are procured but not transplanted, we are concerned with the inclusion of an organ acceptance measure accounting for 20% of a transplant program's overall score in the IOTA Model. First, we note that the inclusion of this measure incentivizes participating programs to focus on deceased donor transplants to increase kidney transplant volume, since the organ acceptance ratio does not include living donor organs. We believe that, because of the superior clinical outcomes, enhanced savings, and untapped potential of living donor transplantation to address the pressing organ shortage, the IOTA Model should prioritize living donor, rather than deceased door transplantation. Certainly, a component that implicitly promotes deceased donor over living donor transplant seems counterproductive.

Second, the IOTA Model proposes to score participating transplant programs in large part based on an "achievement" based scoring system, under which a program's offer acceptance performance would be measured in relationship to the organ acceptance performance of all transplant programs collectively. However, as the draft IOTA Model recognizes, kidney transplant programs vary significantly in terms of size and capability, and not all deceased donor kidney transplant programs are equally capable of achieving positive clinical outcomes when organs at risk of discard are utilized. In fact, transplant programs may specialize, for example, in performing transplants for high BMI, HIV, Hepatitis C+ and other recipients who may require specialized care. We believe that such specialization is in the best interests of patients. However, it is not consistent with the organ acceptance "achievement" measures, which appears to assume that organ acceptance practices should be relatively uniform for all transplant programs regardless of size or capability.

Moreover, we believe that the proposed scoring system is unduly harsh. Organ acceptance practices appear to fall roughly on a bell-shaped curve. Transplant programs performing at the 50th percentile accept organs as predicted by the SRTR model and have a score hovering at 1.0: In the vernacular, these programs are neither too "aggressive" nor too "conservative", but rather accept organs based on donor, recipient, and other clinical factors essentially as predicted by statistical modeling. Yet, a program whose organ acceptance practices are statistically "just right" would earn only 10 out of 20 potential points under the proposed scoring system. Essentially, the proposed scoring system incentivizes all participating programs to accept deceased donor organs significantly more aggressively than the risk adjustment model would suggest—an incentive that has the potential to jeopardize recipient safety and appropriate organ selection practices.

Recommendation: In light of the current variation in organ acceptance practices and the very real differences in the capabilities of different transplant programs to successfully transplant organs at risk of non-use, we believe that, if an organ acceptance domain is included in the final IOTA Model, all transplant programs whose SRTR score is [1.0 or higher] (ie. organ acceptance as expected) should be accorded 20 points, and those scoring less than 1.0 should be scored utilizing an improvement-based scoring system. As performance of those whose scores are less than 1.0 increases, the SRTR model will self-adjust, increasing the number of offers accepted that will be needed to achieve the 1.0 threshold.

V. Quality Domain

Under the proposed IOTA Model, performance on the quality domain would be based on a transplant program's score on three quality measures and on transplant outcomes over the six-year demonstration period.

ASTS is extremely disappointed that CMS chose to include a six-year outcome measure in the draft IOTA Model. During discussions with CMMI over the past several years, ASTS has repeatedly emphasized the adverse impact of that outcomes measures (as reflected in the SRTR five-star rating system and the OPTN transplant program performance criteria) have on transplant programs' perceived ability to accept high risk organs and to transplant higher risk recipients. Yet, the draft IOTA model not only incorporates an outcomes measure in the demonstration design but also extends the period for which transplant programs will be held responsible for outcomes from one year to six years.

Specifically, under the draft IOTA Model, CMS proposes using an unadjusted rolling "composite graft survival rate," defined as the total number of functioning grafts relative to the total number of adult kidney transplants. In this measure, the numerator (observed functioning grafts) and denominator (number of kidney transplants completed) would increase each performance year of the IOTA Model to include a cumulative total performed, to assess IOTA participant performance on post-transplant outcomes.

ASTS strongly objects to the inclusion of this measure in the IOTA Model:

- This outcomes measure imposes on participating transplant programs responsibility for ensuring continuing graft function for a post-transplant period that significantly exceeds the post-transplant period during which transplant programs can reasonably be held accountable for recipients' care. In fact, after the first-year post-transplant, a transplant recipient is typically followed primarily by community nephrologists and other physicians on their health care teams who may or may not be associated with the transplant center.

- The proposed outcome measure is inconsistent with the primary objective of the IOTA Model to increase transplant volumes and reduce disparities. This proposed measure discourages participating transplant programs from transplanting lower quality organs, which are significantly less likely to maintain function for six years post-transplant. Therefore, this measure is inconsistent with the fundamental objectives of the IOTA Model to increase the number of transplants performed and to reduce non-use of lower quality organs. Additionally, the additional mandate to provide six-year data detracts from what should be an unerring and unwavering focus on increasing transplant volumes.

- There is no database that includes six-year post-transplant graft function data. Finalizing this measure as proposed would impose an extraordinary additional data collection burden on participating transplant programs. The six-year follow-up proposal is not concordant with the preexisting monitoring and reporting framework, and it seems illogical to introduce a significant change, as well as an additional unfunded mandate that is incongruent with the strategic goal of the project.

  Recommendation: Eliminate the six-year outcomes requirement in the Model and instead continue to utilize the existing outcomes metrics of 90-day and conditional on 90-day one-year allograft survival, but at a broader range of acceptable outcomes, which will allow centers to accept organs which are at higher risk, given the imprecision of the adjusted survival models currently being utilized

CMS also proposes to select and use three quality measures to assess IOTA participant performance in the quality domain: (1) CollaboRATE Shared Decision-Making Score (2) Colorectal Cancer Screening, and (3) the 3-Item Care Transition Measure.[4] While we

[4] The CollaboRATE Shared Decision-Making Score is a patient-reported measure of shared decision-making. The measure provides a performance score representing the percentage of adults 18 years of age and older who experience a high degree of shared decision making. The CollaboRATE Shared Decision-Making Score is based on three questions that assess the degree to which effort was made to inform the patient of his or her

understand CMS's interest in including quality measures in the IOTA Model, we believe that the cost of reporting these measures will not be insignificant and that these costs constitute an additional unfunded mandate for participating transplant centers. If quality measures are included, we do not believe that the quality measures proposed are appropriate. The colorectal cancer screening measure is only tangentially related to the quality of care provided by transplant programs and the decision making and transition measures have never been tested in that context. If CMS decides that quality measures are necessary, ASTS would be pleased to work with the agency to suggest alternative quality measures better suited to transplantation.

VI. Disparities

The IOTA Model includes multiple features intended to reduce disparities in access to transplantation. For example:

- Under the proposed IOTA Model, each IOTA participant is required to submit a Health Equity Plan (HEP) to CMS for the second performance year, update its HEP for each subsequent performance year and submit progress reports to CMS.

- The proposed IOTA Model includes a health equity performance adjustment under which transplants performed on low-income recipients would "count" as 1.2 transplants for the purposes of determining a participating transplant program's kidney transplant volume.

ASTS strongly supports efforts to reduce disparities in access to kidney transplantation. We believe that this goal can be accomplished most effectively by first identifying and targeting those areas where disparities are most egregious. As emphasized in the NASEM report[5] and as discussed at length during our conversations with CMMI over the past several years, we believe that disparities in living donor transplantation are evident and require immediate attention.

Disparities with respect to deceased donor transplantation present a more complex picture. While we applaud the goals of the health equity performance adjustment, we do have serious concerns regarding its application to measuring a participant's performance

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health issues, to listen to the patient's priorities, and the extent to which the patient's priorities were included in determining next steps. The measure is generic and applies to all clinical encounters.

The 3-Item Care Transition Measure (CTM-3) is a hospital-level, patient-reported measure of readiness for self-care at time of discharge from an acute care hospital. The CTM-3 is based on data from a three-question instrument that assesses whether the patient and family's preferences were accounted for in the care plan; whether patients understood their role in self-management; and, whether appropriate medication education was provided.

[5] https://www.nationalacademies.org/our-work/a-fairer-and-more-equitable-cost-effective-and-transparent-system-of-donor-organ-procurement-allocation-and-distribution.

with respect to deceased donor transplants. The model would include health equity incentives in the form of a health equity performance adjustment in the achievement domain. This adjustment would **give participating transplant hospitals more credit for a transplant performed for a person in a pre-defined, low-income population**. By adding focus on specific populations that are currently less likely to receive a transplant, the model would aim to give patients living with ESRD equitable access to the opportunity for live-saving transplants.

By focusing on the outcome (transplant itself, instead of process (access to the waitlist and the allocation system), this provision will encourage participating transplant programs to identify candidates in the 'pre-defined, low-income population' and preferentially accept kidneys for those patients, to the exclusion of higher-ranked candidates who may not qualify for the adjustment.

In considering whether this adjustment should be finalized with respect to deceased donor transplant volume requirements, it seems pertinent that the racial disparities referenced in the Proposed Rule appear to have extensively mitigated over the past couple of decades, beginning with the changes in allocation priority based on HLA compatibility in the early 2000s.

The good news is that current data shows that overall waitlisting, active waitlisting, and percentage of **deceased-donor** transplants received are essentially equal for Black **ESRD** patients, and equal to the percentage of ESRD patients who are Black. The most recent SRTR Annual Data Report[6] indicates that Black candidates had the highest rate of deceased donor kidney transplant among the defined ethnic/racial groups in 2022 (22.3 per 100 patient-years). In addition, the USRDS 2023 Annual Data Report (2021 data) includes the following data:

ESRD prevalence:

	Percent
White	38
Black	33
Asian	5
Hispanic	20
Other	3

ESRD patients on kidney waiting list:

Group	**Total (%)**	**Active (%)**
White	35	33

[6] https://srtr.org/reports/optnsrtr-annual-data-report/

Black	33	33
Asian	8	9
Hispanic	22	23
Other	2	2

Deceased Donor Transplants:

Group	**Percent**
White	40
Black	32
Asian	6
Hispanic	19
Other	2

Therefore, it appears that racial disparities in the transplant rate and the waiting list are improving.

Unfortunately, disparities in living donor transplantation continue to persist. Living donor transplant is much less common among Black candidates. From the SRTR Annual Data Report[7]:

> *While 31.7% of adult waitlisted candidates on December 31, 2022, were Black, Black patients made up only 12.8% of LDKT recipients versus 34.1% of DDKT recipients that year. White patients made up 35.5% of the waiting list, while 61.4% of LDKT recipients and 35.3% of DDKT recipients were White.*

In addition, Black persons with CKD are much less likely to be waitlisted pre-emptively. As a result, Black candidates with ESRD are less likely to benefit from the higher post-dialysis waitlist priority and are therefore exposed to a longer dialysis tenure prior to eventually receiving a deceased donor kidney.

> **Recommendation**: **We are concerned that the proposed health equity performance adjustments incentivize participating transplant programs to perform transplants out of sequence, giving preferential treatment to low-income candidates, in order to maximize the points they receive on the transplant volume measure. For these reasons and considering the pressing disparities in access to living donor transplants, we urge CMS to consider increasing the adjustment, but limiting the availability of the adjustment to living donor transplants.**

[7] Ibid

VII. Transparency

The IOTA Proposed Model includes multiple features intended to increase the transparency of the transplant process:

- Under the proposed IOTA Model, participating transplant programs are required to make their waitlist criteria public.

- Under the proposed IOTA Model, participating transplant programs must inform each waitlisted Medicare each month of the number of times an organ is declined on the Medicare beneficiary's behalf and the reason(s) for the decline and must provide the same information to the patient's nephrologist or nephrology professional.

  Recommendation: ASTS strongly opposes this component of the proposed Model as untenable from an operational standpoint and counterproductive from a strategic standpoint. ASTS instead strongly supports a requirement that transplant programs make their waitlist criteria public.

While we understand and appreciate the need for increased transparency with respect to organ acceptance practices, we strongly oppose the proposed requirement that participating transplant programs be required to provide monthly notification to each Medicare beneficiary of the times an organ is declined on the beneficiary's behalf. We note that one of the tenets of the Model, and a policy direction supported by the markedly increased numbers of expedited (out of sequence) allocations nationwide, designed to increase system efficiency, decrease non-utilization of procured organs, and increase transplant volume, is completely at odds with this approach. We also note that often an organ is declined for all waitlisted patients on that transplant hospitals wait-list, potentially triggering notification obligation for hundreds or even thousands of patients for large programs for each non-transplantable organ declined. CMMI may not have considered that performing the monthly notifications will require massive expenditure of resources for each program but those notifications themselves will likely produce a massive, propagating follow-on workload for programs as they respond to the flurry of questions from candidates receiving these notifications. The numbers involved are staggering, and while this component of the Model is well-intended, it will create a massive amount of work for transplant programs that will detract from the missions of increasing transplant volume and ensuring quality outcomes. We note that patient groups have emphasized that time-to-transplant and likelihood of receiving a transplant are the metrics they care most about and further note that these data are already publicly reported for all programs (SRTR PSRs).

Recommendation: **While we oppose the proposed requirement for monthly notifications, we believe that it is reasonable for a participating transplant**

program to report its quartile rank with respect to organ offer acceptance to patients on a quarterly or annual basis.

VIII. Applicability of IOTA to Medicare Advantage Enrollees

The IOTA Proposed Rule indicates that participating programs will not be subject to penalties or incentives for transplants performed for Medicare Advantage enrollees. Approximately 50% of all ESRD-eligible Medicare beneficiaries are enrolled in Medicare Advantage plans, and, in some areas, a large majority of Medicare patients are enrolled in Medicare Advantage. Therefore, the exclusion of Medicare Advantage enrollees would significantly limit the financial impact of the IOTA Model and may result in no or little payment to participating providers in areas with high Medicare Advantage penetration, even if they increase transplant volume substantially. Moreover, the exclusion of Medicare Advantage enrollees from the program incentivizes participating transplant programs to transplant Medicare fee-for-service patients over those enrolled in Medicare Advantage. This is particularly troublesome since it appears that the transplantation rates of Medicare Advantage patients are less than expected.

It appears that CMS interprets the Medicare Act to preclude inclusion of Medicare Advantage patients in the model. However, the Medicare Act explicitly excludes organ acquisition costs from Medicare Advantage rates and authorizes the payment of these costs based on the same cost-reporting principles applicable to the organ acquisition costs of fee-for-service beneficiaries. We believe that CMS has the authority to pay (or penalize) participating providers for their performance under the IOTA Model through organ acquisition cost adjustments of participating programs.

We appreciate the opportunity to comment on this important Proposed Rule and look forward to continued dialogue with CMMI regarding refinement of the IOTA Model. If you have any questions regarding these comments, please contact ASTS' Associate Director, Advocacy, Emily Besser, at Emily.Besser@asts.org.

Respectfully,

Ginny Bumgardner, MD, PhD
ASTS President

Attachment B

Figure DD 22: Organ use chart for reported left kidneys, 2023

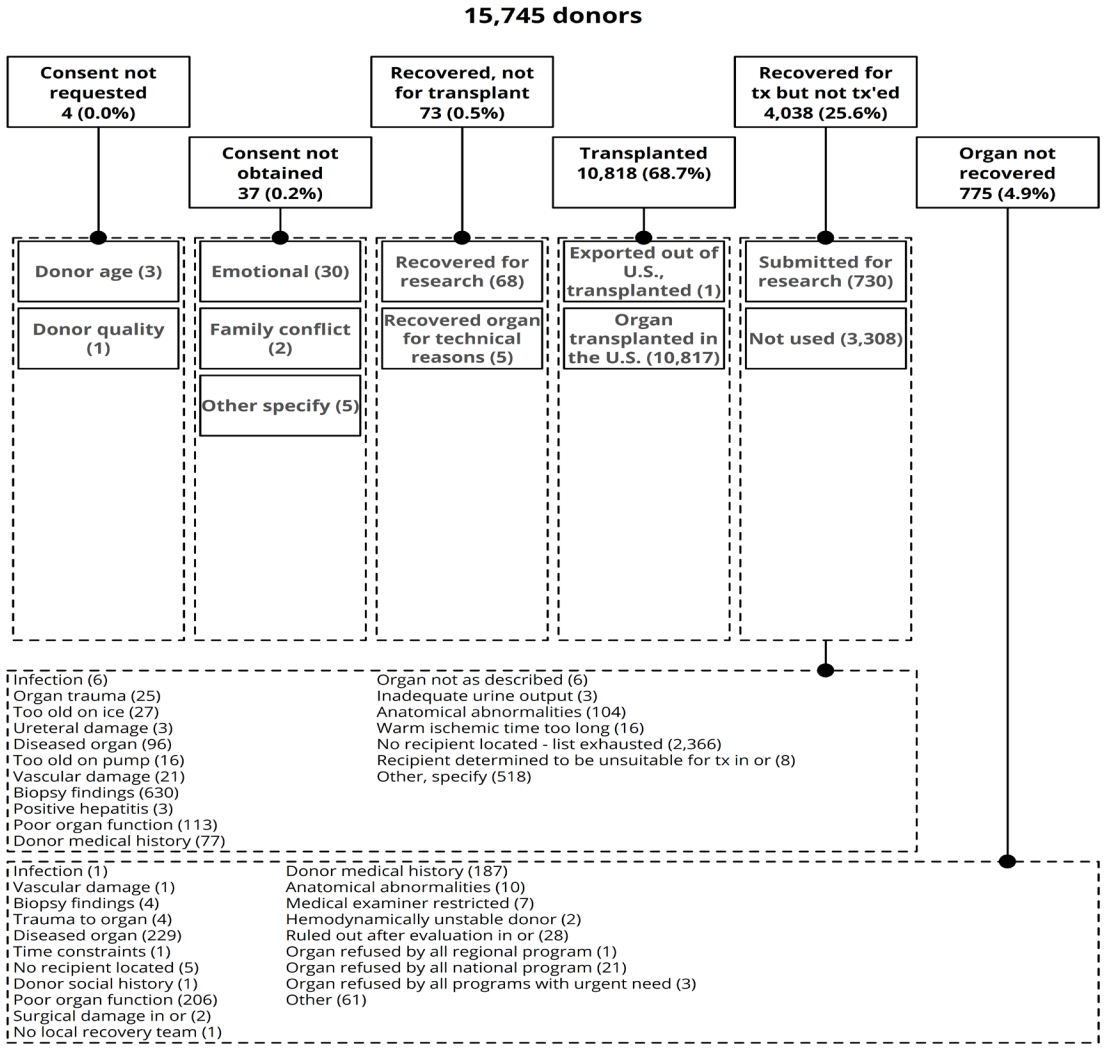

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Figure DD 23: Organ use chart for reported right kidneys, 2023

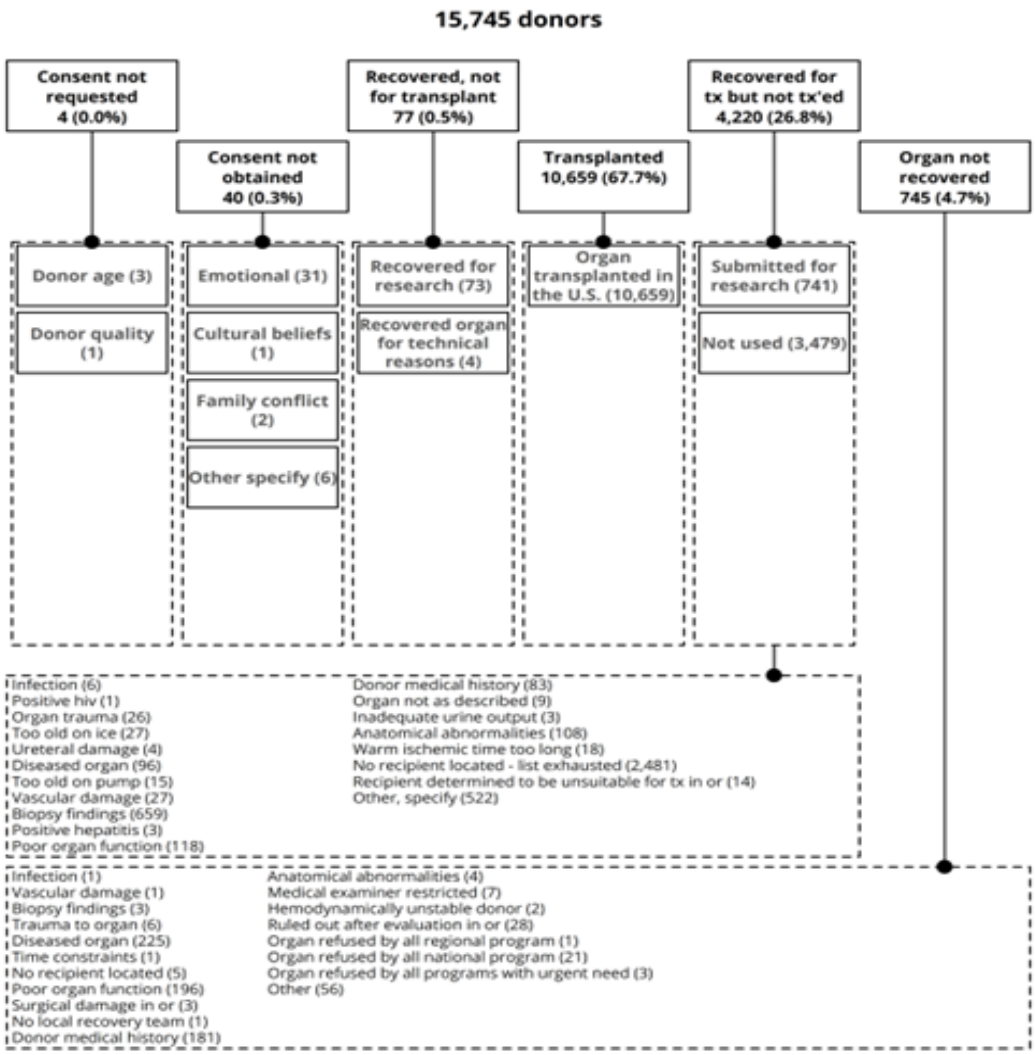

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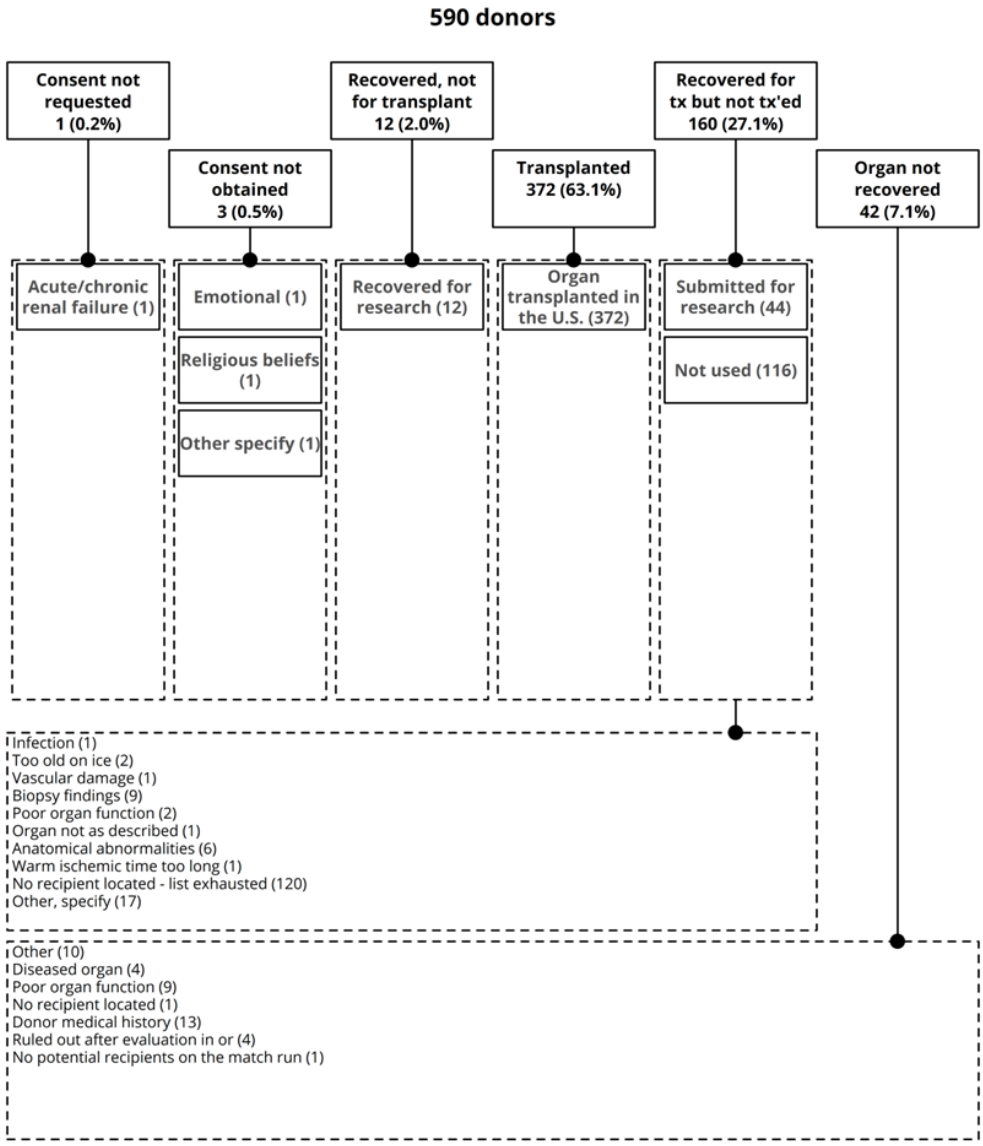
Figure DD 24: Organ use chart for reported en bloc kidneys, 2023



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