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The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5535-P
P.O. Box 8013, Baltimore, MD 21244–8013

Subject: [CMS-5535-P] Medicare Program; FY 2025 Increasing Organ Transplant Access Model (IOTA Model); Federal Register / Vol. 89, No. 97 / Friday, May 17, 2024 / Proposed Rules

Dear Administrator Brooks-LaSure,

On behalf of the more than 200 acute care hospitals in the Greater New York Hospital Association's (GNYHA) membership located in New York, New Jersey, Connecticut, and Rhode Island—17 of which are transplant hospitals—I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed Increasing Organ Transplantation Access (IOTA) model. In 2023, GNYHA member hospitals performed 2,472 kidney transplants[1] and since 2021 have surpassed the national growth rate in kidney transplants.

Our comments focus on the mandatory nature of the IOTA model and its performance and scoring methodologies. We are concerned about the potential unintended consequences of a mandatory payment model on access to kidney transplants and fear that it could amplify existing disparities in resource allocations. The proposed methodology also results in upside potential that is virtually unachievable, particularly for high-performing transplant centers.

If you have any questions or would like further information on GNYHA's recommendations, please contact Rebecca Ryan (212) 506-5514 / rryan@gnyha.org or John Gravina (212)-258-5309 / jgravina@gnyha.org.

Sincerely,

Kenneth E. Raske
President

[1] National data - OPTN. (2024). https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/.

GNYHA Comments on the Fiscal Year 2025 IOTA Proposed Rule

Introduction

CMS is proposing a six-year mandatory payment model, IOTA, for half of transplant hospitals nationwide starting January 1, 2025. The model's goal is to increase access to kidney transplants by maximizing the use of deceased donor kidneys and increase the number of living donors. IOTA hopes to achieve this goal by incentivizing increased transplantation by requiring participating transplant centers to bear the upside and downside financial risk tied to the number of transplants performed, organ acceptance practices, and performance on quality metrics.

GNYHA has significant concerns with the timing, participation requirements, scale, and methodology of IOTA. We urge CMS not to finalize the IOTA model as proposed. If CMS does move forward with the model, we ask that CMS:

- Convert IOTA to a voluntary model
- Revise the performance methodology so that transplant centers have a reasonable chance of success
- Reward both achievement and improvement
- Refine the quality measures by which centers are assessed
- Adjust the requirements for transparency and health equity reporting

Timing

CMS acknowledges that the organ procurement and transplantation ecosystem has undergone significant reforms due to recent regulatory changes, including 1) implementation of the new kidney allocation system in March 2021, which eliminated the use of donation service areas; 2) revisions to the conditions for coverage for Organ Procurement Organizations (OPOs), which allow for the decertification of underperforming OPOs beginning in 2026; and 3) the Organ Procurement and Transplant Network (OPTN) Modernization Initiative. The new kidney allocation system materially changed relationships between transplant programs and OPOs and required transplant centers to make significant investments and changes to processes to account for the influx of offers through the new allocation system. The changes to the conditions of certification and OPTN modernization initiative are likely to have further impacts on the system that may impact the comparability of future performance with targets based on historical data. CMS should wait to implement IOTA until the impact of these reforms is better understood.

Mandatory Participation and Scale

GNYHA opposes mandatory payment demonstrations and recommends CMS structure IOTA as a voluntary model. The overarching goal of IOTA is to increase the number of kidney transplants performed. However, the increases required to exceed the proposed targets under the model are aggressive. The ability of transplant programs to invest in the infrastructure necessary to support these increases will vary greatly between transplant programs. While IOTA offers the opportunity to earn increased reimbursement, it is unlikely that any upside payments earned will provide sufficient incentives to cover the necessary investments. When subject to a participation mandate, providers that are unable to make the necessary investments may be forced to effectively not participate. For these providers, the model is likely to be nothing more than a cut, which risks exacerbating any existing resource disparities. Not only is IOTA proposed to be mandatory, but it would apply to roughly 50% of donation service areas nationally. This

ensures that the program will significantly disrupt a system that is already in the middle of responding to the myriad regulatory changes mentioned above.

As CMS notes, there are two demonstrations that are currently in progress that have similar intent: the Kidney Care Choices Model, which built upon the prior Comprehensive End-Stage Renal Disease (ESRD) Care (CEC) Model, and the ESRD Treatment Choices (ETC) Model. The CEC Model did not directly incentivize transplantation, and evaluations did not measure the impact of the model on transplantation. The ETC program, to date, has not demonstrated the ability to drive meaningful increases in transplantation, and the Kidney Care Choices (KCC) Model has not yet been evaluated. We appreciate the need and clinical benefits of increased transplantation, but we do not believe that CMS should implement a mandatory model of this size without having previously demonstrated the ability of such a program to incentivize increased transplantations relative to expectations. **We understand CMS's concern that participation in the voluntary KCC has been low among transplant hospitals, but rather than mandate participation, CMS should instead focus on designing a model that provides sufficient value to transplant hospitals to incentivize participation**.

While CMS continues to voice concerns about selection bias and program evaluation, we believe that a voluntary program can still provide valuable data and, given the use of appropriate statistical techniques to account for that bias, can provide a reasonable signal of the effectiveness of the program's incentives and justify implementation of a mandatory model.

Performance Assessment and Scoring

CMS proposes to assess each participant based on their performance across three domains: achievement, efficiency, and quality—where achievement is worth up to 60 points, efficiency is worth up to 20 points, and quality is worth up to 20 points for a maximum total score of 100 points. The final score determines the amount of upside or downside risk payment. Each domain has its own set of measures and scoring methodologies, some of which GNYHA finds concerning. Below we highlight our specific comments on each proposed domain. Taken together, **we are concerned that the methodology does not allow for realistic upside potential, largely due to issues with the achievement domain.**

Achievement Domain

The achievement domain is the highest weighted domain; it assesses the number of kidneys transplanted by each IOTA participant in a performance year. CMS theorizes that this would lead to a reduction in deceased donor organ discards and encourage improvement activities to increase the number of living donors. The performance score is calculated by comparing the number of transplants in the performance year to a transplant target, which is adjusted for health equity and the national trend in transplants.

Targets and Trend Factor

CMS proposes to set each participant's performance target by calculating the highest number of transplants furnished in a single year across a three-year baseline period—2021-23 for the first performance year (PY 1)—calculated separately for deceased and living donors and then added together. This number is then trended based on the national growth rate in transplants, should that growth rate be positive. The three-year period would roll forward annually so that the baseline period used for PY 6 targets is 2026-28. Setting performance targets at the maximum number of annual transplants across a rolling three-year baseline period is too aggressive, ignores the myriad factors associated with the number of transplants performed

each year, and results in targets that are unachievable. **CMS should instead use a three-year average across baseline years—a measure that would be more reflective of a participant's expected performance—and hold the baseline period constant instead of moving the goal post each year. If CMS adopts a static baseline, it should establish an extraordinary circumstances policy and/or a baseline adjustment to account for situations that would require a transplant hospital to temporarily suspend operations or drastically reduce volume.**

GNYHA used OPTN data and the Scientific Registry of Transplant Recipients (SRTR) transplant center semiannual reports[2] to assess the performance target methodology. The below example, which uses the data of a GNYHA member transplant center that historically has one of the highest transplant rate ratios in the nation, demonstrates this process. We will refer to this transplant center as "Center A."

Table 1 displays the annual number of deceased, living donor and total kidney transplants performed by Center A in 2021, 2022 and 2023 based on OPTN data and the maximum for each transplant category across that time-period. Table 2 displays an alternative measure, the transplant rate ratio (TRR), from Center A's SRTR January 2022, January 2023, and January 2024 center-specific reports. The TRRs extracted from these reports have performance periods ending in 2021, 2022 and 2023 respectively. The TRR is a risk adjusted measure that indicates whether a transplant center has performed more or less than the expected number of transplants given the number and mix of patients on their waiting list.

Table 1. OPTN Transplants by Year and Donor Status

	Maximum	2023	2022	2021
Deceased Donor Transplants	273	243	273	220
Living Donor Transplants	88	79	62	88
Total Transplants	361	322	335	308

Table 2. SRTR Transplant Rate Ratio by Year

	2023	2022	2021
SRTR Transplant Rate Ratio	2.42	2.09	1.88

Table 1 demonstrates significant variability in the number of transplants, both up and down, from year to year. Between 2021 and 2022, transplants increased by roughly 9%, only to decrease between 2022 and 2023 by 4%. Notably, while transplants appear to have decreased between 2022 and 2023, that has not necessarily been at the expense of the TRR, which compares the observed transplant rate to a risk-adjusted expected transplant rate. Indeed, this transplant center's highest TRR was for the period ending in 2023, the year in which transplants decreased by 4%. This signals that the number of expected transplants in a given year is impacted by contextual factors like organ availability, demand, and changes in patient population that are not captured by a raw count.

As described above, the proposed methodology for setting performance targets would set Center A's performance target, prior to trending, at 361 transplants (273 deceased donor transplants and 88 living donor transplants). The target would then be trended by the national increase in transplants between 2022 and

[2] https://www.srtr.org/reports/program-specific-reports/

2023, which we estimate to be 7.0% based on OPTN data, resulting in an estimated trended target of 386 transplants. This represents a 20% increase in transplants from the prior year. Notably, the TRR in 2023 indicates that this center was already performing roughly 142% more transplants than expected. To increase transplants by a further 20% is unreasonable as a policy goal and most likely not feasible.

The implications of the proposed methodology are clearest when viewed in the context of the model's payment methodology. To be eligible for upside payments, transplant centers need to earn a final score of at least 60 points. If we assume perfect performance in the remaining domains, which is a significant assumption, Center A needs to earn at least 20 points in the achievement domain to reach that threshold and be eligible for any upside. Moreover, to be eligible for the maximum upside payments, Center A would have to increase transplants by 80%, which is an unreasonable expectation.

The proposed use of the national transplant growth rate to trend targets is also problematic. The transplant growth rate varies significantly by OPTN region. These differences cannot be fully explained by transplant center behavior and likely reflect geographic differences in many factors, such as organ donation practices, access to transplant programs, and sociodemographic differences. Moreover, CMS also proposes to apply the trend adjustment only when the trend is positive. This ignores the possibility that transplants may decrease from one year to the next for reasons outside of a center's control. **GNYHA recommends that CMS either remove the national trend adjustment entirely or adjust targets based on the regional growth rate in transplantations to ensure that targets reflect the local potential for increased transplantation. CMS should also adjust for both positive and negative trends.**

Account for Expected Number of Transplants

GNYHA is concerned that the annual number of transplants per year—the only measure proposed for the achievement domain—is not risk adjusted and does not account for contextual changes that may limit a transplant center's ability to increase transplants. **GNYHA recommends that CMS instead use the TRR—the ratio of observed (or predicted) transplants to expected transplants—as the measure of performance in the achievement domain.**

The expected number of transplants is calculated using the SRTR transplant risk-adjustment model, which was developed by SRTR under contract from the Health Resources and Services Administration (HRSA), and accounts for select demographic, social, and clinical characteristics. This expected amount varies from year to year, both up and down, based on the number of individuals on the waiting list and the characteristics of those individuals. By comparing the actual number of transplants to the expected number of transplants, CMS would more accurately reflect the true performance of each transplant center by recognizing that the number of individuals on the transplant waitlist varies from year to year, and that all candidates for transplant are not equally likely to receive a transplant.

Account for Both Improvement and Achievement

The proposed methodology is entirely based on improvement, and it therefore does not recognize providers that historically provide high numbers of transplants relative to expectations, such as Center A. Center A has performed significantly more transplants than expected in each of the three years analyzed, even after accounting for the social, demographic, and clinical differences between the individuals on their waitlist. Under the proposed methodology, there is a significant likelihood that despite performing far more transplants than expected, Center A would be unable to earn bonus payments.

To address this limitation, GNYHA recommends that CMS account for both improvement and achievement. This can be accomplished by implementing a scoring approach similar to the Hospital Value-Based Purchasing (HVBP) program. Under such an approach, transplant centers would be rewarded for either high performance relative to their peers or for improving from a baseline measurement. Assuming CMS accepts our suggestion to switch from a count of raw transplants to the TRR, CMS could award up to 60 achievement points based on the distance between the transplant center's observed and expected rates and up to 60 improvement points based on the distance between the performance year and baseline TRR. The center would then receive the higher of the two amounts as their achievement domain score. This method would reward both centers that are currently performing significantly greater than expected transplants, and therefore may not have the capacity to increase their number of transplants significantly, and those centers that may be performing fewer than expected transplants but are making progress toward the expectation. This would create incentives for providers that are already high performing to remain high performing, and for those who are currently not high performing to improve.

GNYHA recommends that CMS modify the achievement domain by using the TRR and awarding both achievement and improvement. The minimum threshold for receiving full achievement points should not be higher than a TRR of 1.0. Adopting these changes would mean that CMS could eliminate the trend factor because the national rate will improve as those centers that perform below expected move closer to their expected amounts. In addition, expected amounts will account for changes in the national transplant ecosystem as the risk-adjustment coefficients would be updated each year. Furthermore, this method would avoid the issues with setting performance targets identified above, as centers would instead by scored on their performance relative to their expected performance.

Efficiency Domain

The efficiency domain assesses the kidney organ offer acceptance rate ratio (OARR) for each participant, which compares the rate of organ acceptance to a risk-adjusted expected rate of organ acceptance. CMS proposes to score OARR performance in two ways: 1) relative to the OARR of all transplant hospitals ("achievement score") and 2) relative to each participant's own past acceptance ratio ("improvement score"). CMS would award points based on the higher of the two. Transplant centers would earn between 0 and 20 points based on their performance relative to the nation, with centers at or above the 80th percentile receiving the full 20 achievement points. In addition, centers can earn up to 12 improvement points depending on their performance relative to their performance in the third baseline period, with centers earning the full 12 improvement points when they achieve 120% of the TRR in the third baseline period. The domain score is the maximum of the two.

CMS's comparison to the national acceptance ratio assumes that all transplant hospitals are equally capable of achieving positive clinical outcomes with higher risk organs, which is not the case in practice. **We support the use of the OARR, but we recommend that transplant centers with a ratio of 1.0 (i.e., scoring as expected) receive the full 20 achievement points on this domain. In addition, we recommend that CMS allow hospitals to earn up to 20 points based on improvement.** This would allow CMS to focus on providing incentivizes for transplant centers with lower-than-expected acceptance rates and would not penalize centers performing as expected.

Quality Domain

The quality domain awards points based on each center's performance on the following measures:

- a custom composite measure of post-graft survival rate
- the CollaboRATE Shared Decision-Making Score
- a colorectal cancer screening measure (COL)
- the 3-Item Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS)-Care Transition measure (CTM-3)

As described below, **GNYHA recommends that CMS adopt a modified version of the post-graft survival rate measure and eliminate CTM-3. Further, we pose clarifying questions and raise potential concerns about the COL measure.**

Post-Graft Survival Rate

GNYHA is concerned that the proposed post-graft survival rate lacks risk adjustment. SRTR has developed comprehensive risk adjustment methods for post-transplant outcomes, including post-graft survival rate. The SRTR risk-adjustment model undergoes regular testing and is updated annually. The current incarnation of the model recommends adjustment for both donor and recipient characteristics, including:

- Donor and Recipient demographic characteristics such as age, gender, and race
- Donor and recipient clinical characteristics such as BMI, past behavior, medication history, and history of certain conditions

CMS recognizes that graft survival is dependent on these characteristics but does not adjust for them. CMS notes that the inclusion of risk adjustment was considered but not ultimately included in the proposal in part because there is no risk-adjustment model with consensus approval in the kidney community. While we recognize that there have been some critiques of the SRTR model's accuracy, we do not believe that an unadjusted measure of post-graft survival is reasonable. **We encourage CMS to either implement the current SRTR risk-adjustment methodology or work with HRSA and SRTR to refine their risk-adjustment model to alleviate concerns from the kidney transplant community and include the measure only after it can be accurately risk adjusted.**

Additionally, the proposed post-graft survival metric is cumulative, and therefore by the end of the proposed model period, transplant centers will be accountable for graft survival up to six years after some transplants. We do not believe this timeframe is reasonable. Post-transplant care more than one year after transplant is generally the domain of the recipient's nephrologist and is no longer in the control of the transplant facility. In fact, we believe that the inclusion of a six-year post-transplant graft survival rate outcome measure is at odds with the model's goal of increasing the number of kidney transplants. CMS expressed concern in the proposed rule that low organ acceptance rates could be linked to the use of transplant graft and recipient survival measures. Yet, CMS is introducing a post-transplant outcomes measure that spans a longer period than the one- and three-year graft survival measures that are currently used in the SRTR. If CMS wants to increase the number of kidney transplants in part by encouraging transplant centers to accept higher risk organs, it should remove the proposed measure and instead continue to use the existing post-transplant

survival measures. This would also reduce the additional reporting burden associated with a new quality measure.

HCAHPS CTM-3

GNYHA does not support the inclusion of the HCAHPS CTM-3 in the IOTA model. First, CMS recently proposed to remove the CTM-3 from the HCAHPS survey beginning with patients discharged January 1, 2025, and replacing it with a new three-item care coordination sub-scale.[3] We do not believe that CMS should include a potentially antiquated measure in a value-based payment program of this size. Second, the CTM-3 and the HCAHPS survey has not been validated for the kidney transplant population and is intended for use in the overall hospital patient population. It is unclear whether this measure will produce accurate and valid results when applied to a smaller complex population. Finally, while CMS states that the use of the CTM-3 will allow providers to take advantage of existing infrastructure, this is likely overstated. The introduction of a sample that is unique from the random sample that hospitals currently survey will require significant changes to existing workflows, including changes to vendor training and contracting.

Colorectal Cancer Screening (COL)

CMS proposes to require transplant hospitals participating in IOTA to annually administer the COL measure to their attributed transplant patients. Based on our understanding of the proposal, to satisfy the requirements for this measure, transplant centers would need to assess if any attributed transplant patient has been screened for colorectal cancer in each year of the programs. We are concerned that this would require transplant centers to ascertain whether transplant patients had been screened for colorectal cancer up to six years after they received their transplant (for those individuals receiving transplants in the first year of the model). **GNYHA does not believe that it is appropriate to hold transplant centers accountable for monitoring COL rates up to six years after transplantation.** It is likely that community nephrologists will provide a significant amount of post-transplant care rather than transplant centers, and therefore it is unclear how transplant centers will obtain this information. In addition, the Healthcare Effectiveness Data and Information Set specifications for the COL measure indicate that COL is an administrative measure, but CMS includes a "response rate" for the pay-for-reporting years of this measure. **We ask CMS to clarify how a response rate will be calculated for an administrative measure and how this differs from the target that will need to be achieved after the measure turns pay for performance.**

Duplication and Administrative Burden

GNYHA is concerned that the proposed quality measures must be fielded on the organization's entire attributed population. This is particularly concerning considering the proposal to allow for patients to be attributed to multiple transplant centers when listed on more than one waitlist. We believe that duplicative collection of quality data on individuals included on multiple wait lists is wasteful and will result in needless burden on both hospitals and patients.

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[3] https://www.federalregister.gov/documents/2024/05/02/2024-07567/medicare-and-medicaid-programs-and-the-childrens-health-insurance-program-hospital-inpatient.

Additional Requirements

CMS also proposes transparency, public reporting, and health equity plan requirements for participating hospitals. The transparency requirement asks an IOTA participant to publish on a public website the criteria used for adding a patient to a waiting list, in addition to disclosing the number of organ offers received and declined on the patient's behalf monthly with appropriate reasoning. For the health equity requirement, CMS proposes that IOTA participants submit a health equity plan (HEP) identifying health disparities within its attributed population and establishing an action plan to address them.

GNYHA is concerned about the requirement to notify patients of organs declined on their behalf. The same organ can be declined for multiple, and sometimes all, patients on a hospital's waitlist. Requiring providers to explain intricate decisions for a high volume of patients could drastically increase the administrative load on health care providers, undermine patients' trust, and induce unnecessary stress whenever a kidney is declined for justifiable clinical reasons.

GNYHA is concerned about the increased administrative responsibilities and duplicative burden associated with submitting HEPs. Hospitals are already subject to health equity requirements at the facility level. In addition to the rules and regulations that inform the provision of equitable care, the CMS Inpatient Quality Reporting program includes a new measure on hospital commitment to health equity, which captures hospital data collection, analysis, and quality improvement practices. Additionally, accrediting organizations such as The Joint Commission have now incorporated health equity into their standard hospital survey criteria, capturing similar elements.

While GNYHA appreciates CMS's desire to align this program with other Innovation Center models that increasingly include a HEP, we have concerns about how this HEP would be evaluated and used by CMS and the resources that would be necessary to meet the HEP expectations outlined in the proposal. In the proposal, CMS establishes a target timeframe of 60 business days for its review and approval of plans; however, it later indicates that it "may reject the health equity plan or require amendment of the health equity plan at any time, including after its initial submission and approval." While hospitals would certainly want to address any CMS questions and concerns about their health equity activities, knowing that plans could be rejected or amended at any time is highly risky for our hospitals, which will be putting considerable time and effort into the development of these plans. The proposal includes that if a program participant fails to meet the requirements of the HEP, the participant would be subject to remedial action such as recoupment of any upside risk payments or termination from the model. **GNYHA asks that CMS remove that uncertainty from this model. The concept of a HEP being tied to a CMS program is a new paradigm. GNYHA appreciates that HEPs would be voluntary in PY 1 and asks that CMS provide additional guidance on its expectations for the HEPs upfront.**