



**FRESENIUS
MEDICAL CARE**

Global Medical Office

VIA ELECTRONIC SUBMISSION

May 29, 2024

The Honorable Chiquita Brooks-LaSure

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-5535-P

Re: Request for Information; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model

Fresenius Medical Care appreciates the opportunity to respond to the Request for Information (RFI) titled *Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model* issued by the Centers for Medicare & Medicaid Services (CMS).

In the RFI, CMS contemplates a new alternative payment model applied to kidney transplant hospitals that would "...test whether performance-based incentive payments paid to or owed by participating kidney transplant hospitals increase access to kidney transplants for patients with end-stage kidney disease (ESKD) while preserving or enhancing the quality of care and reducing Medicare expenditures."

As the largest integrated supplier in the country of services and products for individuals undergoing dialysis due to End Stage Kidney Disease (ESKD), Fresenius Medical Care has long been involved in advocating for vulnerable kidney disease patients, many of whom suffer comorbidities and belong to communities that have been historically underserved and marginalized. We appreciate CMS's consideration of a system-wide approach to developing quality metrics and two-sided risk models which prioritizes increasing the total volume of kidneys transplanted while safeguarding patient outcomes and addressing durable inequities in access to transplantation. We agree that more can be done to align incentives across the transplant ecosystem with the goal of a more equitable system that provides more transplants to all patients in need.

We appreciate the opportunity to provide feedback to CMS on this proposed payment model. Though we proffer several criticisms, concerns, and constructive suggestions for improvement on specific aspects of the IOTA Model, on the whole Fresenius Medical Care is very supportive of the main facets of the model as proposed. Fresenius Medical Care leaders have long been proponents of policy changes which serve to improve patient access to transplantation by dismantling the care coordination silos between general and transplant nephrologists^{1,2} and aligning incentives and continuity of care delivery across the entire continuum of kidney disease.³ Fresenius Medical Care believes that the proposed IOTA Model is largely consonant with our stated and published positions in this regard.

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1. CMS seeks comment on the proposed model performance period of 6 years and the proposed model start date.

Fresenius Medical Care believes the proposed model performance of 6 years is appropriate, as is the start date of January 1, 2025, for the reasons outlined by CMS

2. CMS seeks comment on codification of the definitions in 42 CFR part 512 subparts A & D.

Fresenius Medical Care believes codifying the definitions and policies of the IOTA model under the referenced statutes is appropriate for the reasons outlined by CMS.

3. CMS seeks public comment on the proposal that the IOTA Model participants would be kidney transplant hospitals.

Fresenius Medical Care believes CMS's proposal that IOTA Model participants would be kidney transplant hospitals is appropriate. Kidney transplant hospitals are the locus of financial remuneration for and regulatory oversight of kidney transplantation and is therefore the appropriate entity to be enrolled in and held accountable for performance in the IOTA Model.

4. CMS seeks public comment on our proposal to make participation in the IOTA Model mandatory.

Fresenius Medical Care is on record as preferring voluntary value-based care payment models.⁴ However, we do understand CMS's contention that participation in the IOTA Model should be mandatory, since it is possible that voluntary participation only will select for motivated transplant programs, the absence of mandatory enrollment may result in few incentives for less motivated transplant programs to adjust behaviors. The *raison d'etre* of the IOTA Model is to improve performance and behaviors amongst high and low performers

¹ <https://pubmed.ncbi.nlm.nih.gov/28898574/>

² <https://pubmed.ncbi.nlm.nih.gov/31561276/>

³ [https://www.kireports.org/article/S2468-0249\(24\)00093-7/fulltext](https://www.kireports.org/article/S2468-0249(24)00093-7/fulltext)

⁴ <https://doi.org/10.1016/j.ekir.2024.02.004>

alike, and improving the performance of lower performing transplant programs is a more urgent public policy matter. But, the IOTA Model as proposed renders termination from the Model for non-performance an outcome which offers no meaningful downside to enrolled transplant programs. In essence, mandatory participation may be undermined by the absence of any meaningful adverse consequences for termination. While terminated transplant programs would be liable for financial penalties assessed in a given PY, transplant programs uninterested in participating in the model may simply accept “a fine as a price,” and exit the Model without further consequence.

5. CMS seeks comment on our proposed participant eligibility criteria for kidney transplant hospitals, including the requirement that a kidney transplant hospital perform 11 or more kidney transplants annually on patients aged 18 years or older during the baseline years, and the exclusion of pediatric-only centers.

Fresenius Medical Care concurs with the exclusion criteria outlined by CMS, for the reasons cited in the proposed Rule.

6. CMS seeks comment on the proposed approach for selecting IOTA participants.

Fresenius Medical Care concurs that Donor Service Areas (DSAs) are the appropriate geographic division for selecting IOTA participants, as DSAs more readily map to the extant reporting and regulatory rules and policies for kidney transplant programs, compared to HRRs for example. We also concur with the proposed stratification by volume of kidney transplant programs, though we would note there may be some unforeseen/unintended consequences of advantaging programs classified as “low volume” where the volume is close to the low/high volume dividing line, and vice versa. We also suggest the dividing line between low and high volume should be revisited by CMS across PYs, since the expectation is that the volume of transplants will increase in enrolled transplant programs, whether or not they are classified as low or high volume at the beginning of the model. We concur, generally, with the proposal to group DSAs into Census Divisions and randomly select 50% of transplant programs to be enrolled in the IOTA Model.

7. CMS seeks public comment on our proposals to include all adult kidney transplant waitlist patients, regardless of payer type and waitlist status, who are alive, and registered on a waitlist to an IOTA participant. CMS also seeks comment on using transplanted patients who are similarly attributed to IOTA participants for the purposes of scoring and determining performance-based payments. CMS also seeks comment on IOTA waitlisted patients, allowing multiple attributions for multi-listed patients, and attribution/de-attribution criteria.

Fresenius Medical Care generally concurs with the attribution approach proposed by CMS for both waitlisted and transplanted patients. We believe this “all payer” attribution approach for the purposes of scoring performance across the quality domains is a real virtue of the IOTA model. We agree with quarterly attribution reconciliations with an omnibus annual reconciliation at the end of each PY. Finally, we agree with CMS’s proposal to allow multi-listed patients to have multiple attributions to IOTA participants, and avoid distinctions based

on waitlist “status,” etc. for the reasons outlined in the Rule. We concur with CMS’s proposal to attribute transplanted patients age > 18 who are alive and allow for the possibility of patients with a failed transplant to become IOTA attributed candidates again.

However, as we discuss elsewhere, using patients with Medicare FFS coverage (primary or secondary) and excluding patients with Medicare Advantage. (MA) plans for the purposes of determining performance-based payments should be reconsidered. The prevalence of Medicare-eligible patients with MA plans has been steadily increasing, and there is little reason to suppose these trends will abate over the 6-year duration of the IOTA Model. As more patients elect for MA plans and (by extension) fewer patients retain Medicare FFS plans, both the upside bonus payments and (already anemic) downside penalties predicated on the number of transplanted patients with Medicare FFS plans will be further attenuated over time. For the purpose of this comment, we propose that CMS revisit pursuing a waiver to SSA 1851(i)(2) to allow bonuses and penalties to be imposed on the number of IOTA attributed patients with either Medicare FFS or MA coverage.

8. CMS seeks comment on our proposed achievement domain performance metric and alternative methodologies considered for assessing transplant rates.

Fresenius Medical Care concurs with CMS’s proposed achievement domain performance metric and underscores our support for CMS’s desire to “...test the effectiveness of the model’s incentives to change outcomes, rather than on processes.” We believe benchmarking Center participants based on historical performance with national growth and health equity modifiers is appropriate and has the virtue of simplicity and ease of understanding for stakeholders.

However, Fresenius Medical Care believes the achievement thresholds as outlined in “Table 3: PROPOSED ASSESSMENT OF ACHIEVEMENT DOMAIN,” are too aggressive and will sharply curtail any Center’s opportunities for achieving more than 30 points in any PY. By way of illustration, we modeled a hypothetical large volume transplant center that had a maximum 100 living donor kidney transplants and 250 deceased donor kidney transplants from 2021-2023. The estimated IOTA historical volume benchmark = 350. Adding in a 3.5% “national growth” modifier for 2024 would increase the historic volume benchmark “transplant target” to 362 transplants. So, this hypothetical enrolled Center would need to perform 125% more transplants, or 452 total transplants in a PY for an Achievement Domain score of 45. A one-year increase of 90 kidney transplants would make this hypothetical Center one of the largest two or three programs in the country by volume. Putting upside payments so far out of plausible reach will have the effect of attenuating any effects on Center behaviors.

As an alternative, Fresenius Medical Care recommends reducing the Achievement Domain Thresholds accordingly:

Performance Relative to Transplant Target	Lower Bound Condition	Upper Bound Condition	Points Earned
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125% of transplant target	Equals 125%	N/A	60
100% of transplant target	Equals 100%	Less than 125%	40
75% of transplant target	Equals 75%	Less than 100%	20
75% of transplant target	N/A	Less than 75%	0

Fresenius Medical Care believes this alternative approach allows enrolled transplant programs increasing their total transplant volume by > 100% of an already high threshold to realize upside benefits in a more reliable and realistic manner, which in turn would improve the efficacy of the “upside” incentive in positively modifying Center behaviors.

9. CMS seeks comment on the proposed health equity performance adjustment, the definition of low-income population and alternatives considered, and consideration of ADI as an alternative definition, and including rural resident in the low-income population definition.

Fresenius Medical Care concurs with CMS’s proposal for an “upside only” health equity performance adjustment and endorses the definition of “low-income population” outlined in the proposed Rule. We concur with CMS’s decision not to include the ADI due to the limitations of the ADI as outlined by CMS. Fresenius Medical Care recommends that CMS consider including “rural resident” as a group comprising a “low income” population for the purposes of the IOTA model, since rural residency is associated with significant barriers to transplantation, a situation only made worse by the increasingly precarious hospital footprint in rural areas of the country.

10. CMS seeks comment on our proposal to use and calculate the OPTN organ offer acceptance rate ratio for assessing Efficiency Domain performance, and attendant proposed definitions in the rule.

Fresenius Medical Care concurs with CMS’s proposal for the organ offer acceptance rate ratio for Efficiency Domain performance, with some modest suggestions for improvement. Generally speaking, we believe the proposal as written both (a) encourages enrolled transplant programs to increase the rate of acceptance of organs offered and (b) encourages enrolled transplant programs to tailor their organ offer filters in a manner that more accurately reflects the Center’s organ offer acceptance behaviors, while still allowing transplant programs the flexibility to liberalize their organ offer filters in an effort to increase their forward-looking organ acceptance rates. Fresenius Medical Care also agrees with excluding “bypassed response” offers based on Center-prescribed organ offer filters. This exclusion of “bypassed response” offers from the Efficiency Domain measure provides a

needed firewall between CMS’s policy goals and leaving clinical decision-making discretion to transplant professionals.

Fresenius Medical Care respectfully disagrees with CMS’s decision to use the “Probability of Organ Offer Acceptance” formula as a means of including in the Efficiency Domain metric. As far as we can tell, the c-statistic of the SRTR’s “Risk Adjustment Model: Offer Acceptance” tool has not been published; In any event it is not available on the SRTR website. Given past performance of “risk adjustment” tools such as the KDRI (c-statistic 0.6 for graft survival, evidence of increased discards for KDPI > 85 kidneys after the KDPI was widely available) we recommend caution in embracing new risk models prior to peer-reviewed validation of predictive accuracy. Instead, we suggest CMS calculate the organ offer acceptance rate by dividing the number of organs each IOTA participant accepts by the number offered to that transplant hospital’s patients that are ultimately accepted elsewhere. We understand this approach may raise concerns about the absence of “risk adjustment” and the possibility of “unfairness” to some IOTA participants. But, if IOTA participants choose to be more aggressive in their organ offer filters and organ offer acceptance practices, they can modify behaviors accordingly. If not, not.

11. CMS seeks comment on the proposed organ offer acceptance rate ratio performance scoring methodology for purposes of assessing efficiency domain performance for each IOTA participant, including on the achievement and improvement score calculation and point allocation method.

Fresenius Medical Care generally agrees with CMS’s approach to apportioning points for the organ offer acceptance rate for both achievement and improvement. Specifically, we agree with prioritizing absolute achievement over improvement, though as mentioned, we recommend CMS abandon the SRTR equation. We note that transplant programs could improve their Efficiency Domain performance with tighter organ offer filters, but this approach would likely disadvantage the Center on the Achievement Domain metric, which is appropriately weighted more heavily. In any event, enrolled transplant programs who nevertheless elect for more conservative organ offer filters will confer a net benefit to the organ offer system: If all enrolled transplant programs have organ offer filters that accurately reflect current organ offer acceptance behaviors, system-wide improvements in the efficient placement of organs will likely follow.

12. CMS seeks public comment on the proposal to evaluate IOTA participants on post-transplant outcomes using the new composite graft survival rate metric.

Fresenius Medical Care concurs with CMS’s proposal to calculate post-transplant outcomes using a rolling, unadjusted, cumulative graft measure. While we are confident that many commenters will argue for an urgent need to add “risk adjustment” of one stripe or another to the measure, the proposed measure has the virtues of being simple, clear, easy to understand, and easy to explain to patients and families. We believe these virtues are, too often, under-emphasized. Next, the cumulative feature of the post-transplant survival metric ensures that

differences in post-transplant graft and patient-survival between enrolled transplant programs would have to be quite substantial over time to demonstrate any conspicuous absolute separation. The fact is more aggressive organ acceptance and utilization behaviors will almost certainly result in future patient and graft survival outcomes that are inferior to current rates, but nevertheless superior to survival on maintenance dialysis. Fresenius Medical Care believes the salient “control arm” for post-transplant patient/graft survival should be maintenance dialysis. CMS’s proposed post-transplant outcomes metric may result in higher patient and graft survival rates among conservative programs, but higher volume/higher risk tolerant programs will be benchmarked against a greater rolling numerator and denominator of total transplants and are therefore less likely to be disadvantaged even without risk adjustments. Furthermore, nothing in the IOTA Model replaces the extant regulatory oversight framework administered by the OPTN. transplant programs which fall afoul of existing quality metrics for patient and graft survival will still hear from the MPSC. The IOTA Model as proposed does not “over-engineer” on this point.

13. CMS seeks public comment on how to use OPTN data to characterize different clinical manifestations of graft survival, as we understand that not all surviving grafts are clinically equivalent or have the same impact on the patient and graft health.

To repeat the last sentence of our last comment: The IOTA Model as proposed does not “over-engineer” on this point, and it should not. There are, obviously, different clinical manifestations of graft survival. If unintended/undesirable trends emerge in the out years of the model, CMS can propose subsequent adjustments.

14. CMS seeks public comment on the proposed point allocation and calculation methodology for post-transplant outcomes within the quality domain for the IOTA Model and alternatives considered.

Fresenius Medical Care concurs with CMS’s approach to the point allocation and calculation methodology for post-transplant outcomes.

15. CMS seeks comment on the proposed quality measure set that includes two PRO-PMs (CollaboRATE Shared Decision-Making Score and 3-Item Care Transition Measure) and one process measure (Colorectal Cancer Screening) for purposes of measuring performance in the quality domain, and proposed alternatives. CMS also seeks comment on the proposed scoring system for the Quality Domain.

Fresenius Medical Care recognizes CMS’s need to include patient reported outcomes (PRO), but we also note that neither the CollaboRATE Shared Decision-Making tool nor the 3-Item Care Transition Measure have any evidence base for use in kidney transplantation nor in patients with chronic kidney disease nor end-stage kidney disease. While CMS notes the Patient Activation Measure (PAM) does not have an evidence base which supports its use in kidney transplant candidates, the same could be said for all three of the proposed measures in the Rule. At least, in the case of the PAM, there is now a body of experience using the tool in patients with CKD or ESKD enrolled in the voluntary KCC models. We note that at least

one study measuring the effect of a “stop-and-think” approach to validating CollaboRATE tool ⁵concluded that “Reflection-before-quantification interventions may not improve the performance of patient-reported measures of SDM with substantial ceiling/halo effects.” This does not auger well for the CollaboRATE tool as a useful measure, much less an effective driver, of actual shared decision making. While the 3-question tool is certainly “lightweight” in terms of implementation, it may well prove equally lightweight in terms of significance. Similar characterizations could be made of the 3-Item Care Transition Measure, which (to just select one example) has been shown to have only very weak associations with post-hospital discharge outcomes⁶. Including measures without any convincing evidence base for efficacy as part of a Quality Domain metric may be counterproductive and discourage support for PRO measurements generally.

Obvious as it may be, it is worth stating: Effective social interventions to improve “active” waitlist status that are focused on patient activation and self-care within the patient’s control require more focused attention and methodologically sound study. CMS should take the lead in engaging (and funding) social scientists who formally research patient-reported outcomes and generate a methodologically sound and context-specific measure and that can be implemented, initially as a reporting measure only and subsequently as a Quality Domain measure for the purpose of assessing shared decision making about patient-focused risk tolerance regarding organ offer quality. One example of a sound and context-specific measure of shared-decision making about organ offer risk tolerance is the patient preference model employed by Mehotra et al. in assessing the organ offer risk tolerance of kidney transplant candidates⁷. While not “lightweight,” it is considerably more germane than the CollaboRATE tool in addressing a key area of policy concern. Whether using this tool and ensconcing it as a reporting measure is another matter. The iChoose Kidney tool was found to improve patient knowledge about transplantation but had no impact on transplant access⁸.

In summary, rather than imposing empirically implausible and/or context-generic PRO measures, CMS should engage the social science and patient communities to generate methodologically sound and context-specific PRO measurements tools for improving transplant access. The general principles governing CMS’s proposed scoring system for the Quality Domain are reasonable, but contingent on and secondary to the actual value of the selected PRO measures themselves.

16. CMS seeks comment on the proposed two-sided risk payment design to incentivize model performance goals.

Fresenius Medical Care generally agrees with CMS’s proposal to implement a two-sided risk payment design. We disagree with how CMS has proposed to implement both upside and downside risk payments, which we discuss below.

⁵ <https://pubmed.ncbi.nlm.nih.gov/31414553/>

⁶ <https://pubmed.ncbi.nlm.nih.gov/31420825/>

⁷ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9625104/>

⁸ [https://www.amjtransplant.org/article/S1600-6135\(22\)09656-3/fulltext](https://www.amjtransplant.org/article/S1600-6135(22)09656-3/fulltext)

17. CMS seeks comment on the proposed methodology to calculate the upside risk payment and alternatives considered.

Fresenius Medical Care notes there may be two typos in the Rule describing the equations for the upside payments to IOTA enrollees: On p. 10 and p. 27 of the .pdf, the Rule references an upside payment formula thus: “CMS would apply the formula for the upside risk payment, which we propose would be equal to the IOTA participant’s final performance score minus 60, **then divided by 60**, then multiplied by \$8,000....” (emphasis ours). Throughout the rest of the rule, the **numerator is divided by 40** (see pp. 171, 292, 341). We assume the latter represents CMS’s original intent.

Fresenius Medical Care respectfully disagrees with CMS’s proposed approach to upside risk payments. First, we believe the “neutral zone” score range of 41-59 is too broad and should be narrowed such that fewer transplant programs receive a “neutral zone designation and more transplant programs are subject to upside payments and downside financial penalties. This could be accomplished in any number of ways, but the point is that IOTA enrollment is more likely to change Center behaviors if the likelihood of both bonuses and penalties for transplant programs is increased. Second, we disagree that the (correct) formula for upside financial bonuses is a “...large financial incentive to promote behavior changes.” It is not.

By CMS’s own estimates (Table III in the rule), upside risk payments will amount to \$5M-\$7M per PY, spread out over 90 enrolled transplant programs. By our estimates, given the breakdown of Domain achievements and point allocations it is unlikely that even very high performing transplant programs across all Domains will achieve a score > 75. A score of 75 would result in a bonus = \$3000 * total Medicare FFS transplants in a PY. As we previously mentioned, the total number of Medicare FFS transplants (defined in the Rule as Medicare being primary or secondary payer) is shrinking and likely to continue to shrink due to the increasing prevalence of patients with Medicare Advantage plans. In some markets, the prevalence of MA plans in Medicare-eligible patients with ESKD approaches 50%. It is well recognized that transplanted populations are over-represented by patients with traditional commercial plans compared to the overall ESKD population. Pegging the upside bonus payments to only the total number of transplants with Medicare FFS will keep per-Center upside payments low and likely to shrink over time proportional to the growth of MA plan share in this population.

Consider the example of a Center which performed 150 kidney transplants in a PY. For that Center, say that achievement amounted to 135% of the Center’s calculated transplant target, and the Center achieved $\geq 80^{\text{th}}$ percentile on the organ offer acceptance rate and Quality Domain Metrics, resulting in a combined score across 3 Domains of 75, an exceptional cross-Domain performance by any measure. The Center’s payor mix includes 40% MA, 25% traditional commercial, and 30% Medicare FFS, and 5% Medicaid only. The total annual upside bonus for the Center would be: $(75-60/40 * \$8,000) * (150 \text{ kidneys} * 0.3 \text{ Medicare FFS}) = \underline{\$135,000}$. A Health Equity bonus was not included in this scenario, but reasonable projections along these lines would not affect the dollar figure that much. That total bonus might cover the salary and benefits of one additional transplant RN coordinator in most markets.

It is worth reiterating what the IOTA Model is designed to fix: Durable inequities in access to transplantation, particularly among younger patients who are Black and Hispanic, which have persisted for more than two decades⁹. (Half of all currently waitlisted patients have a Status 7 designation. One recent study from ESKD Network 6 showed that 50% of referred patients never start an evaluation ~24 months after referral, and of those patients that start an evaluation, only 30% are waitlisted ~12 months later¹⁰. It is implausible that a \$135,000 annual bonus paid for exceptional performance will meaningfully offset the costs of system-level resources and interventions needed to address these deep systemic inefficiencies in pre-transplant upstream processes as well as the significant resource deficits in (less lucrative) downstream post-transplant care and care transition resources.

We recommend CMS consider other, non-mutually exclusive alternative approaches to calculating upside payments: (1) Seek and obtain a waiver from SSA 1851(i)(2) and count transplanted patients with Medicare Advantage coverage for the purposes of calculating upside payments. (2) Change the denominator for calculating the total points modifier from (Total points -60/40) to (Total points -60/4). (3) As previously discussed, narrow the scoring band for “neutral zone” designation, which would increase the number of enrolled transplant programs subject to either upside bonus payments or downside penalties. We recognize this will result in substantially higher cost estimates to CMS for the model on a PY and aggregate basis. We recommend CMS make use of existing “break even” financial models to compare the costs of maintenance dialysis to a functioning transplant in future “pay for” calculations, and that CMS consider QALY adjustments to transplant-related payments for the purposes of “pay for” calculations.

18. CMS seeks comment on the proposed downside risk payment calculation formula, and alternatives considered.

In commenting on the proposed rule, CMS notes that “...we wanted to maintain a greater rewards approach, while still holding IOTA participants accountable for poor performance.” Fresenius Medical Care believes the proposed downside risk payment calculation formula fails to hold IOTA participants accountable in any meaningful way. By CMS’s own estimates, the total amount of collected downside penalties through PY6 will only amount to \$1M. (Table III, p. 294). CMS also notes that they considered higher downstream penalty formulas, but “...opted against it to maintain lower levels of risk given the fact that this model would be mandatory for eligible kidney hospitals.” We are unsure why CMS is reluctant in this particular instance to include meaningful downstream financial penalties simply due to mandatory enrollment.

Enrolled transplant programs who simply abstain from IOTA participation and risk “termination” from the model may, per the current draft Rule, be liable for a downstream penalty in the PY of termination and may possibly have to refund upside financial bonuses in prior PYs. But these transplant programs could simply treat this fine as a (very inexpensive) price to pay for wholly avoiding accountability through 2031. In addition, the same

⁹ <https://pubmed.ncbi.nlm.nih.gov/33574159/>

¹⁰ <https://pubmed.ncbi.nlm.nih.gov/34039566/>

phenomenon of a shrinking pool of patients with Medicare FFS coverage attenuating upside bonuses also has the same effect of attenuating downside penalties.

Fresenius Medical Care recommends that CMS reconsider its current approach to calculating downside penalties. We recommend that at a minimum, CMS consider applying the same fixed amount (\$8,000) to the downside risk payment calculation. We also recommend that any changes to the “patients transplanted” basis for calculating upside payments be equally applied to downside penalties. We propose that CMS change the denominator for calculating the total points modifier from (40-total points/**40**) to (40-Total points/**10**). This approach would result in lower total downside risk liability compared to total upside bonus payments, while also rendering the downside penalties more meaningful to enrolled transplant programs without being financially catastrophic. Finally, we also propose a modification to the Model which would allow enrolled transplant programs be provided the opportunity to forebear their downside penalties in a given PY through a to-be-defined mitigation process which combines process improvement with performance improvement over a defined time frame (e.g. 6 months) which if successfully completed would allow transplant programs to “zero out” their downside penalties for a prior PY. The number of mitigation processes a given transplant program can pursue can be capped, and forbearance payments could accrue interest in the event the transplant program failed to satisfactorily complete the mitigation process as determined by CMS or a third-party assessor so designated by CMS.

19. CMS seeks comment on the proposed payment operations and timeline and alternative considered.

Fresenius Medical Care agrees with the proposed payment operations and timeline outlined in the Rule.

20. CMS seeks comment on the proposals regarding the process by which an IOTA participant could request a targeted review of CMS calculations.

Fresenius Medical Care agrees with the proposals as stated in the Rule regarding the process by which an IOTA participant could request a targeted review of CMS calculations.

21. CMS seeks comment on the additional privacy, security, breach notification, and other requirements that is proposed for inclusion in the data sharing agreement.

Fresenius Medical Care agrees with the privacy, security, breach notification, and other requirements that is proposed for inclusion in the data sharing agreement.

22. CMS seeks comment on what specific disclosures of the beneficiary identifiable data might be appropriate to permit or prohibit under the data sharing agreement.

Fresenius Medical Care generally agrees with the proposed permissions and prohibitions on disclosures of beneficiary-identifiable data outlined in the Rule, though we have concerns about prohibiting disclosures to “...an individual practitioner in a treatment relationship with the attributed patient who is a Medicare beneficiary, or that practitioner’s business

associates.” Care coordination is a key component of improving access to transplantation, and such disclosure permission may be an important part of building these care coordination systems. Prohibiting disclosure of this information to practitioners or partners of practitioners in a therapeutic relationship with the beneficiary may unintentionally foreclose efforts at bridging care coordination gaps.

23. CMS seeks comment on the proposal to impose certain requirements in the IOTA data sharing agreement related to privacy, security, data retention, breach notification, and data destruction.

Fresenius Medical Care agrees with the proposal as outlined in the Rule, to impose certain requirements in the IOTA data sharing agreement related to privacy, security, data retention, breach notification, and data destruction.

24. CMS seeks comment on whether an alternative frequency of sharing of organ offers with the Medicare beneficiary is more appropriate, what frequency may best be appropriate, and whether the disclosure requirement should be limited to beneficiaries who have or are likely to receive an organ offer in the next year.

Fresenius Medical Care believes that the monthly notification requirement outlined in the Rule is a reasonable compromise. Fresenius Medical Care does not think that “real time” or even “as soon as possible” is a reasonable or operationally realistic requirement to impose on transplant programs. We would suggest (though this may have unintended consequences) that CMS consider limiting the disclosure responsibility to a certain threshold position of a waitlisted candidate on a given match run. Match runs in UNet can run into the thousands of patients per organ offer. We would tentatively propose limiting the disclosure requirement to the first 100-200 candidates lexically ordered on the initial match run. We recognize that lexical order in the match run can change in real time based on the transplant program’s offer responses, and fully appreciate this may not be a readily operational alternative. We offer this suggestion (or an alternative version in the same vein) to reduce the burden of reporting declined organ offers in circumstances where the candidate was highly unlikely to receive the primary organ offer in the first place. Fresenius Medical Care does not agree with limiting disclosure to beneficiaries who have or are likely to receive an offer in the next year, simply because the dynamics of organ offers has changed significantly since the introduction of KAS 250. We agree with and are sympathetic to the policy goal of reducing unnecessary burdens (to patients and physicians) of disclosing declined organ offers to hundreds of candidates who were unlikely to receive the offer as a primary organ offer in the first place. It is likely there is no perfect solution to this challenge which balances all considerations appropriately.

25. CMS seeks comment on the intent, manner, timing, and content of IOTA Model information posted to the CMS website.

Fresenius Medical Care concurs with the intent, manner, timing, and content of web postings about IOTA Model enrollees as outlined in the proposed Rule.

26. CMS seeks comment on whether a requirement should be included for IOTA participants to conduct HRSN screening and report HRSN data in a form and manner specified by CMS each PY for their attributed patients. We are seeking input on following the questions in this section, and comment on any aspect of the psychosocial evaluation of waitlisted patients and how this compares to HRSN screenings for the four domains – food security, housing, transportation, and utilities.

Fresenius Medical Care generally agrees that imposing HRSN data reporting requirements for transplant programs would be redundant, given the concomitant requirements of a psychosocial evaluation for each referred patient being considered for waitlisting. In general, transplant psychosocial evaluations are comprehensive and often in narrative form which can make population-level data extraction difficult. Rather than impose this blanket requirement on transplant programs, we believe the concomitant requirements on transplant programs to develop and submit a “Health Equity Plan” for approval by CMS is a more “ground up,” and context-specific systems-level approach to addressing SDOH concerns.

27. CMS seeks comment on the potential impact of creation of a health equity plan, whether such plans should be voluntary, and whether health equity plans should only be a requirement in later PYs of the IOTA Model.

Fresenius Medical Care generally agrees with the proposal in the Rule to delay the initial Health Equity Plan submission to CMS to PY2. We would recommend that a comprehensive Plan be submitted in PY2 with clear and measurable endpoints which can be submitted in a more concise fashion to CMS on an annual basis in subsequent PYs, with the option for the Center to supplement subsequent PY submissions with narrative commentary, as the Center (or CMS) deem necessary. We would encourage CMS to furnish, well in advance of the submission deadline, complete examples of sample Health Equity Plan submissions that are acceptable.

28. CMS seeks comment on the proposed requirements for beneficiary notifications.

Fresenius Medical Care agrees with the proposed requirements for beneficiary notifications.

29. CMS seeks comment on the proposed definition of IOTA collaborators and any additional Medicare-enrolled providers or suppliers that should be included in this definition.

Fresenius Medical Care agrees with the proposed definition of IOTA collaborators as listed in the Rule.

30. CMS seeks comment about all provisions described in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met. CMS also seeks comment on the anticipated effect of the proposed compliance program requirement for IOTA collaborators, particularly with regard to

individual physicians and nonphysician practitioners, small PGPs, NPPGPs, and TGPs and whether alternative compliance program requirements for all or a subset of IOTA collaborators should be adopted to mitigate any effect of the proposal that could make participation as an IOTA collaborator infeasible for any provider, supplier, or other entity on the proposed list of types of IOTA collaborators

Fresenius Medical Care agrees with the safeguard provisions outlined in the Rule, and we do not identify any obvious unintended consequences of implementing the described compliance and mitigation programs outlined in the Rule.

31. CMS seeks comment on the proposed definition of IOTA activities as an inclusive and comprehensive framework for capturing direct care and care redesign that contribute to performance across the achievement domain, efficiency domain, and quality domain.

Fresenius Medical Care agrees with the utility of defining “IOTA activities” broadly, as described in the Rule.

32. CMS seeks comment about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

Fresenius Medical Care agrees with the safeguards as outlined in the Rule, and we are not proposing additional safeguards.

33. CMS seeks comment on this proposal for gainsharing payments, where the methodology could take into account the amount of IOTA activities provided by an IOTA collaborator relative to other IOTA collaborators.

Fresenius Medical Care agrees with CMS’s proposal for gainsharing payments as outlined in the Rule. As written, the Rule makes it very clear that gainsharing payments (or fractional amounts therein) may not be used for influencing volume or value referral patterns. Methodological questions about relative contributions of IOTA collaborators should be established through an appropriate contractual arrangement, with clear language outlining the proscription on influencing referral patterns.

34. CMS also seeks comment on our proposed aggregate and individual IOTA collaborator limitations on alignment payments.

Fresenius Medical Care recommends the proposed limit of 50% of payments be an upper limit on upside bonus payments, rather than limiting the payment to IOTA collaborators such that it “...must not exceed 50 percent of the IOTA participant’s downside risk payment.” Given the negligible downside risk exposure in the current model design, the current proposal would result in nearly no permissible payments to IOTA collaborators as a practical matter. As an alternative, CMS could either apply the 50% limit to upside bonus payments to

the IOTA participant, or (our preference), CMS could fix the downside penalty equation in the manner we argued for in our response to comment #18, above and apply the 50% limit to the (revised) downside penalty equation. We respectfully disagree with the proposed limitation of 25% of the PY to an individual IOTA collaborator. These are negotiations and limits which should be left up to the discretion of the parties.

35. CMS seeks comment on the proposed GAAP accounting standards and methods of funds transfer, as well as a series of documentation requirements for IOTA participants.

Fresenius Medical Care agrees with CMS's proposal on GAAP accounting, funds transfer methods, and documentation requirements as outlined in the Rule.

36. CMS seeks comment on including that the anti-kickback safe harbor for CMS-sponsored model arrangements (§ 1001.952(ii)(1)) be available to IOTA participants and IOTA collaborators.

Fresenius Medical Care strongly concurs CMS's proposal that AKS safe harbor provisions be made available to both IOTA participants and IOTA collaborators.

37. CMS seeks comment on proposed provisions regarding proposed grounds for remedial actions, remedial actions generally, and whether additional types of remedial action would be appropriate.

Fresenius Medical Care agrees with CMS's proposal for grounds for remedial action, type of remedial actions, and we are not proposing additional types of remedial action.

38. CMS seeks comment on the inclusion of a HRQOL patient-reported outcome measure in the IOTA Model, as well as on the inclusion of an access to waitlist measure.

Fresenius Medical Care concurs with CMS's comment that "...there remains significant information gaps in understanding how PROMs are, and can be utilized across different domains, especially within nephrology to enrich patient-centered care, and measure other important quality components, such as access to transplantation, shared-decision making and quality of life post-transplantation, to provide a comprehensive understanding." In the absence of PROMs with a convincing evidence base supporting application in these areas, we concur with the conclusions of Brett et al.¹¹: "Patients and caregivers will need to be involved in this process to ensure that transplantation quality metrics encompass the broad domains of healthcare quality and measure what is important to not only healthcare professionals but to patients and their families." We strongly recommend that CMS pursue patient and family stakeholder input in conjunction with social science experts before proposing or implementing a particular HRQOL PROM, with a clear plan for reporting, tracking, and

¹¹ <https://pubmed.ncbi.nlm.nih.gov/29557915>

validation in advance of postulating particular PROMs for required reporting or quality benchmarking.

39. CMS generally requests comment on metrics measuring “upstream” access to the transplant waiting list, e.g. referral, evaluation, and ultimate disposition of referral and evaluation, for the purpose of future rule making.

Fresenius Medical Care appreciates the opportunity to comment on this complex topic. As a general matter, our experience has been that transplant centers currently do not lack for patient referrals. Swaths of transplant community leaders have warned against policy-driven efforts to create default opt-out approaches to transplant referral, primarily because kidney transplant programs are insufficiently resourced to reliably and efficiently disposition the current volume of patient referrals. Nearly any metric that might be proposed incentivizing transplant referral would likely devolve into a blanket policy of referring nearly all patients. From an operations standpoint, a default/opt-out approach to transplant referrals would vastly simplify matters for referring general nephrology practices and dialysis providers. But, we believe a policy requirement along these lines would inevitably overwhelm a transplant center intake and evaluation system already under considerable strain, resulting in downstream inefficiencies which would slow down the evaluation and transplant process for all patients. However, we do believe referral, evaluation, and waitlist practices can be made more operationally efficient and cost effective. To this end, we would refer CMS to a recent manuscript which proposes a novel approach to the “referral-evaluation-waitlist” or “REW” continuum as a component of a broader “transplant-inclusive” value-based care payment model, posed as a successor model to the KCC model upon their expiration at the end of 2027¹².

We appreciate the opportunity to provide feedback on the IOTA Model. Please do not hesitate to contact us if you have any questions or if you wish to discuss our comments in more detail.

Sincerely,



Benjamin Hippen, MD, FASN, FAST

Senior Vice President, Global Head of Transplant Medicine, and Emerging Capabilities

Fresenius Medical Care.

¹² [https://www.kireports.org/article/S2468-0249\(24\)00093-7/fulltext](https://www.kireports.org/article/S2468-0249(24)00093-7/fulltext)