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Advancing Health in America

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The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Submitted Electronically

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

Dear Administrator Brooks-LaSure,

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to provide feedback on the proposed Increasing Organ Transplant Access (IOTA) Model.

Our members have long supported the Center for Medicare and Medicaid Innovation (CMMI) in testing innovative payment models to improve health care quality and reduce costs. However, to accomplish these objectives, models must be carefully designed to ensure that they align with intended goals, are feasible to implement and do not have unintended negative consequences. In fact, we have recommended that CMMI consider common principles in developing such models to make participation more attractive for potential participants. We are concerned that the IOTA model would not meaningfully advance the move to value.

IOTA's goal of increasing access to kidney transplants is one that the AHA shares. However, we are concerned that many of the model design features may in fact exacerbate inequities and negatively impact patients' quality of care. We are particularly concerned that the model's heavy focus on transplant volume may incentivize unintended consequences, such as sub-par matches. **Given the potential negative**

impact on patient outcomes, we urge CMMI to not implement the IOTA model at this time. As written, it is not fully developed and contains fundamental flaws.

The proposed rule's most problematic design elements are delineated below and explained more thoroughly in the attached.

- **IOTA would add unnecessary disruption and uncertainty to the transplant ecosystem, which is already undergoing significant transformation.** The organ transplant ecosystem is undergoing massive transformation under the Organ Procurement and Transplantation Network (OPTN) Modernization Initiative and Securing the U.S. Organ Procurement and Transplantation Network Act. These changes will result in significant workflow, staffing and reporting modifications for stakeholders, including hospitals. Implementing a mandatory organ transplant payment model simultaneously as these transformations would add risk and uncertainty to a complex and critical portion of the care continuum.

- **IOTA's timeline is untenable.** Complex (not to mention successful) payment model implementation requires significant time, resources and staffing by hospital participants. But, CMMI has proposed an IOTA start date of Jan. 1, 2025 — less than six months from now and an even briefer time from when the rule will be in its final form. It would notify participants of their mandatory participation with as little as three months' notice. Given the organ transplant system's transformation already occurring as mentioned above, this aggressive timeline is untenable.

- **IOTA's mandatory participation is inappropriate.** Hospitals must be able to assess whether CMMI models are appropriate for their patients' and communities' needs. Yet, the proposed rule would mandate certain hospitals' participation in IOTA. Specifically, it would require participation for certain kidney transplant hospitals with 11 or more kidney transplants in a three-year baseline period — a threshold that does not come close to ensuring statistical significance and exposes organizations to unwarranted penalties for outlier cases.

- **IOTA's emphasis on volume could incentivize sub-par matches and exacerbate inequities.** As proposed, IOTA heavily emphasizes transplant volume increases. Specifically, 60% of a hospital's performance score would be determined by transplant volume. To receive a maximum score, the hospital would need to increase historical volume by 150% plus a national growth rate. By so heavily incentivizing increases in the number of transplants performed, we are concerned that CMMI is also incentivizing sub-par organ matches. Moreover, we are concerned that the lack of an appropriate risk adjustment incentivizes the selection of healthier patient populations and could exacerbate existing

inequities concerning who receives transplants, which impacts underserved and geographically remote transplant facilities.

- **IOTA's other proposed measures run counter to CMS' goal of broadening access to transplants and are discordant with other regulatory requirements.** IOTA has built-in conflicting metrics by including measures such as offer-acceptance ratios and graft survival rates. On the one hand, the model would heavily incentivize volume increases, but on the other, offer-acceptance ratios would incentivize more conservative selection of organs for transplants. The methodology for these other measures also differs from the standards and reporting requirements established by OPTN.

Our members are committed to improving access and reducing disparities in kidney transplants. However, the proposed IOTA model not only would fail to help achieve these goals but also may result in reduced quality and exacerbated care inequities. **As such we recommend that CMMI not implement this model at this time. Instead, CMS should evaluate, after implementation of changes under the OPTN modernization initiative, the need for a voluntary payment model.** That way, CMS would understand areas where further reform may be needed and could effectively test the model without confounding variables.

Our detailed comments are attached. Please contact me if you have questions or feel free to have a member of your team contact Jennifer Holloman, AHA's senior associate director of policy, at jholloman@aha.org.

Sincerely,

/s/

Ashley Thompson
Senior Vice President
Public Policy Analysis and Development

Cc: Elizabeth Fowler
Director, CMMI

INCREASING ORGAN TRANSPLANT ACCESS MODEL TABLE OF CONTENTS

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BACKGROUND

Kidney transplants occur within a broad transplant ecosystem including Organ Procurement Organizations (OPOs), transplant hospitals and providers, donor hospitals, dialysis facilities, histocompatibility laboratories supporting testing for organ matching, donors, patients in need of a transplant, and OPTN. This ecosystem is undergoing a massive transformation as mandated under The Securing the U.S. Organ Procurement and Transplantation Network Act of 2023. The Health Resources and Services Administration (HRSA) has requested vendor proposals to support changes to the governance, technology and operation of OPTN. For the past 40 years, many of these functions have remained under the purview of the current vendor, United Network for Organ Sharing (UNOS). HRSA also directed UNOS to standardize and update data reporting for greater accountability and equity in organ procurement and transplant practices.

These changes will result in significant workflow, staffing and reporting modifications for stakeholders in the transplant ecosystem including donor hospitals and transplant providers. **Introducing a mandatory payment model on top of the existing modernization initiatives would add unnecessary disruption, risk and uncertainty to a complex and critical portion of the care continuum.**

MODEL PERFORMANCE PERIODS

CMS proposes a six-year model performance period, beginning Jan. 1, 2025, and ending Dec. 31, 2030. Under this proposal, participants may have as little as three months' notice that they would be required to participate in IOTA. **A three-month on-ramp for an alternative payment model (APM) is not feasible.** Implementation of complex APMs requires significant time and resources to support. Participants must have adequate time to implement care delivery changes (integrating new staff, changing clinical workflows, implementing new analytics tools, etc.) and review data before initiating the program. Given the proposed emphasis on volume increases, there would also be staffing requirements to support (administrative staff as well as clinical staff) and potential capital requirements to support additional operating room suite capacity. Three months is inadequate to analyze resource needs, let alone integrate requirements into budgets. Previous models have had much longer on-ramps to prepare for implementation. Indeed, the Kidney Care Choices (KCC) model, which is voluntary, solicited applications in October 2019, and the first performance period began in January 2022.

The unrealistic timeline is another reason why this model should not be implemented. If CMS were to pursue implementation anyway, then the on-ramp should be extended. Specifically, hospitals should have at least one year to prepare for the model as part of pre-implementation and at least two years of upside-only risk.

PARTICIPATION AND MARKET SELECTION

CMS proposes that eligible participants would include kidney transplant hospitals. Eligible kidney transplant hospitals would include those that perform 11 or more transplants for patients 18 years or older annually across payers across three baseline years and perform more than 50% of kidney transplants annually to patients over 18 years old across baseline years. All kidney transplant hospitals meeting eligibility criteria in selected geographic areas would be required to participate in the IOTA model. **We oppose CMS' proposal to make participation in IOTA mandatory. If CMS pursues implementation of the model against the AHA's recommendation, then participation should be voluntary.**

Mandatory Participation Can Negatively Impact Hospital Financial Stability and Patient Care. Certain hospitals may not be in a position to make the infrastructure investments necessary to be successful in the model nor to absorb potential losses. IOTA may harm a variety of hospitals, from those serving underserved communities (due to the lack of appropriate risk adjustments in the performance score metrics), those with a high volume of transplants (since the achievement targets are untenable), and those with a low volume of transplants (due to the potential impact of outliers). The potential upside payments are small enough that they do not adequately cover costs to support the infrastructure necessary to succeed while the downside risk can result in payment cuts that place programs at risk and may ultimately result in reduced patient access. In fact, a Government Accountability Office report found that mandatory participation in APMs could negatively impact patient care and financial sustainability if participants cannot leave the model. It also found that mandatory participation could negatively impact organizations' ability to support other voluntary models for which they may be better equipped.

Mandatory Participation Can Increase Disparities for Underserved Populations. Model design features that we describe below, like the lack of risk adjustments across performance score measures, would cause organizations like safety-net hospitals and those serving higher proportions of dual-eligible (DE) and low-income subsidy (LIS) beneficiaries to be penalized under this model simply because of the patient populations they serve. This runs afoul of the explicit goal of the program, which is to increase access to organ transplants.

Mandatory Participation Can Harm Low Volume Hospitals. While the proposed rule includes a low-volume threshold, it is insufficient. A low-volume threshold should ensure that hospitals have enough cases to integrate changes in care delivery and determine if they have an impact based on statistical significance. Additionally, it should ensure that the costs associated with standing-up infrastructure for model participation (like analytics infrastructure and staffing) can be offset by potential gains in the model. Financially, it also should protect against outliers and volatility inherent in small sample sizes. **A threshold of 11 cases across three years is too low and fails to meet any of these criteria.** The rationale cited for selecting 11 as the low-volume threshold was

simply that many hospitals performed between 11 and 50 per year, not that 11 generated an adequate sample size to ensure statistical significance or any other reasonable rationale. **If CMS does move forward with IOTA, we urge it to increase the low-volume threshold to ensure statistical significance and effectively mitigate potential impacts of outliers and volatility in cases. Hospitals not meeting the low-volume thresholds should be excluded from participation in the model, so they are not unnecessarily exposed to financial risk for factors beyond their control.**

ATTRIBUTION

Patients would be attributed to IOTA model participants based on their registration for transplant waitlists or completed transplant procedures. Patients would be attributed through an initial attribution process and then quarterly. Attribution lists would then be reconciled retrospectively after the end of the performance year.

The Proposed Timelines for Attribution List Updates Is Unreasonable. CMS proposes that initial attribution lists would be provided a mere 15 days in advance of the start of the performance period. This does not provide a sufficient amount of time for hospitals to prepare. **If CMS were to move forward with the model, attribution lists should be provided at least one quarter in advance of the start of the performance period.**

In addition, CMS proposes that reconciliation attribution lists would be provided prior to the second quarter of the following performance year. This is also challenging. Hospitals would not know which patients were attributed to their organizations until six months after the conclusion of the performance year. This would severely limit their ability to improve performance since they would not know with certainty which patients were included in their performance score calculations. **If CMS does move forward with IOTA, attribution lists should be provided in advance of performance periods so that organizations could impact performance.**

IOTA PERFORMANCE ASSESSMENT

CMS proposes to assess each IOTA participant's performance across three performance domains in each performance year of the model, with a final maximum possible score of 100 points. The achievement domain would be worth up to 60 points, while the efficiency and quality domains would be worth up to 20 points each. CMS would use the final performance score in its performance-based incentive payment formula to determine whether participants receive an upside risk payment, no risk payments or owe a downside risk repayment to CMS.

Throughout the proposed rule, CMS asserts that its performance assessment approach would reduce inequities in kidney transplant rates for underserved patients, ensure more patients benefit from transplantation, and improve the quality and experience of kidney transplant care. Yet, CMS' proposal to base the majority of IOTA participant

scores on aggressive transplant volume targets — and the remainder on inadequately validated quality measures — could inadvertently undermine CMS' laudable goals for the IOTA model. **The AHA opposes CMS' proposed IOTA performance assessment approach and believes it is one of the many reasons CMS should not proceed with the IOTA model at this time.**

Achievement Domain. This performance domain includes only one measure — the number of kidney transplants performed on adults 18 years and older compared to a historical target, subject to a health equity adjustment. CMS would use all-payer OPTN and Medicare claims data to calculate the number of kidney transplants performed by the IOTA participant during a performance year. Participants with less than 75% of their target number of transplants during the performance year would receive zero points while those performing at 150% or more of their target number would receive the maximum 60 points.

The IOTA model's heavy emphasis on increasing the volume of kidney transplants is paradoxical given CMS and CMMI's long-standing interest in advancing care models focused on improving value, not volume. CMS' use of a volume measure appears to stem from a well-intentioned goal of helping more patients benefit from kidney transplants. However, the AHA is concerned for multiple reasons that CMS' proposed approach introduces risks that far outweigh any benefits.

First, available data show that the available kidney supply is insufficient to sustain a year-on-year 150% transplant volume increase. In other words, the design of the achievement domain makes it impossible for all participants to receive 60 points for achieving 150% of their historical target number. As illustrated below, OPTN data suggest that there is not an adequate supply of kidneys to support such an aggressive growth target nationally.[1] Specifically, using the proposed IOTA methodology and OPTN data to simulate the baseline period of 2021 to 2023, the highest number of deceased and living donor transplants was in 2023, totaling 28,144 (see Table 1).

Table 1. OPTN Data on Number of Kidney Transplants, 2021-2023

Year	# Deceased Donor Transplants	# Living Donor Transplants	Total # Transplants	Growth Rate
2021	19,519	5,971	25,490	7.81%
2022	20,446	5,864	26,310	3.22%
2023	21,854	6,290	28,144	6.97%

[1] https://insights.unos.org/OPTN-metrics/

When adjusting for the national growth rate from 2022-2023 (6.97%) and the 150% growth target, the national target for the increased number of transplants would be 45,158 (see Table 2).

Table 2. Projected National IOTA Targets for Achievement Domain

Unadjusted Kidney Target ((Highest Deceased Donor Transplants + Highest Living Donor Transplants) * National Growth Rate 2022-2023)	IOTA Participant Achievement Target Percentages	IOTA Participant Achievement Target Numbers
30,106	Greater than 150%	45,158
	125%-150%	37,632
	100%-125%	30,106
	75%-100%	22,579
	Less than 75%	22,578

Even when making the most favorable assumptions, there would not be enough kidney supply nationally to support this aggressive target. Specifically, in 2023, there were 6,293 living kidney donors and 15,471 deceased kidney donors (see Table 3). Even when assuming organ quality, adequate match and two kidneys per deceased donor, the estimated 37,235 kidneys would not be sufficient to support the 45,158 target proposed by IOTA.

Table 3. OPTN Data on Number of Kidney Donors 2021-2023

Year	# Living Donors	# Deceased Donors	Estimated # Kidneys*	Growth Rate
2021	5,971	13,215	32,401	
2022	5,862	14,227	34,316	5.91%
2023	6,293	15,471	37,235	8.51%

**Assumes that deceased donors would generate two kidneys for transplant*

Indeed, the kidney supply would need to increase by over 21% in a single year to have an adequate kidney supply to meet the target on paper. This projected shortage would be much larger considering the nature of our assumptions, namely that there would be some kidneys that do not meet quality standards and do not have adequate matches and that not all the deceased donors would donate two kidneys. In effect, CMS' proposal assumes there is an unlimited supply of kidneys, which is, of course, inaccurate. Furthermore, not all geographies are equal in supply and potential for increased kidney donations through living donors. The distribution of underlying comorbidities that limit suitability for kidney donation is not equal, and some communities may not be able to increase the number of living donors in their geographic area due to the higher prevalence of chronic disease. Ultimately, the very nature of transplants is complex and represents a weaving of not only supply and demand but the intersection of matches and quality assessment to ensure that an organ

transplant will be accepted. Furthermore, some transplant hospitals must also account for logistics like drive times and distance from donor hospitals and OPOs.

CMS' proposed approach to defining the national growth rate in determining the historical target also could make the targets even more unachievable, especially during the first two performance years of the model. For example, the national growth rate in performance year one would be the percent change in transplant volume in 2023 compared to 2022. During 2022, hospitals and health systems were grappling with the impacts of the once-in-a-century COVID-19 public health emergency (PHE) that placed significant downward pressure on their surgical and other procedure volumes. However, as the PHE wound down, hospital procedural volumes began to rebound. In the context of the IOTA model achievement domain, we are concerned that the historical growth rate from 2022 to 2023 would be exaggerated, resulting in target transplant numbers that could be excessively high. The national growth rate for performance year two also could be non-representative given that the PHE fully concluded on May 11, 2023, and surgical volumes continued their rebound from historical lows.

Lastly, the AHA is concerned that weighting the achievement domain much higher than any other domain heightens the incentive for clinically suboptimal matches between recipients and donated organs. Certainly, the IOTA performance assessment approach includes measures other than volume, including organ offer acceptance ratio, composite graft survival rate, and others. Yet, by design, no single performance measure would carry as high weight as the transplant volume measure. In real terms, the composite graft survival rate measure included in the quality domain (worth 10 points) carries *six times less weight* in determining IOTA participant performance than transplant volume (worth 60 points). Similarly, the organ offer acceptance ratio measure in the efficiency domain (worth 20 points) carries *three times less weight* than transplant volume. Ultimately, increasing equitable access to transplant care is the right goal, but this goal should not be achieved at the expense of quality. CMS' current approach fails to achieve this important balance.

The AHA also believes CMS may be underplaying the critical role of patient choice in transplantation. As we understand CMS' theory, a volume-based metric could encourage hospitals to have conversations with patients about transplanting a wider range of potentially matched kidneys, including those that may not have as long-lasting a positive impact as more optimally matched organs. Ultimately, it is patients — in consultation with their families and care team — that must decide whether a particular kidney is right for their needs and circumstances. This conversation is always complex, involves numerous clinical and personal tradeoffs and sometimes results in patients opting against accepting a particular transplant offer. This is especially true for clinically complex patients and those considering multi-organ transplants. In other words, the pursuit of a higher number of transplants — especially a dauntingly high increase from previous years — will not necessarily yield as many transplants as CMS believes possible.

Health Equity Performance Adjustment. With a stated purpose of incentivizing IOTA participants to decrease disparities in the overall transplant rate for low-income and underserved patients, CMS proposes to include a health equity performance adjustment. Specifically, in calculating the number of transplants an IOTA participant performs during a performance year, CMS would multiply by 1.2 any transplants provided to patients that are: uninsured, on Medicaid, dually eligible for Medicare and Medicaid, recipients of the Medicare Part D low-income subsidy, or are recipients of reimbursement from the Living Organ Donation Reimbursement program administered by the National Living Donor Assistance Center.

As a general principle, the AHA appreciates CMS' emphasis on advancing health equity in this model. However, given our overarching concerns about using transplant volume as a performance metric, we do not support CMS' proposed health equity adjustment. Furthermore, while CMS' inclusion of uninsured patients in the health equity performance adjustment is well-intentioned, the overall design of the IOTA model does not lend itself to addressing this barrier. Indeed, a lack of insurance coverage often is an insurmountable barrier to achieving successful transplantation outcomes. While CMS' equity bonus is intended to incentivize hospitals to deliver transplants to uninsured patients, we note that the bonus payments under the model pale compared to the costs of the complex and ongoing care that all transplant patients require for successful outcomes. Indeed, transplant care is about much more than transplant surgery. Patients require preoperative testing and monitoring, dietary counseling and medications, among other things. Following the procedure, patients take immunosuppressive drugs to ensure their bodies do not fight the newly transplanted kidney. One study estimates the average cost for outpatient immunosuppressants and other drugs was nearly $32,000 in 2020. Further, just as before the operation, patients need ongoing testing, monitoring and clinician office visits following a surgery. Certainly, hospitals and health systems always work with patients to try to overcome financial barriers to care access, including by working with them to gain insurance coverage if they lack it. However, a lack of insurance coverage presents a major challenge for patients and hospitals alike in achieving better kidney care outcomes.

Additionally, CMS' proposal fails to consider difficulties for those living in remote, rural or mountainous communities sometimes at a great distance from the transplant hospital making it difficult or impossible for a patient to accept an offered organ. Such geographic consideration may lower the offer acceptance rate for some transplant centers, and not be remediable by the transplant center regardless of how motivated it might be to achieve more transplantations. CMS' proposal may disadvantage rural or frontier residents needing kidney transplants and the centers that strive to provide the care they need simply because CMS' model emphasizes volume over value.

Efficiency Domain. CMS' stated goals with this domain are to encourage IOTA participants to accept as many kidneys for transplantation as possible, to reduce the number of unused kidneys and to reduce observed disparities in who receives kidney

transplants. To achieve these goals, CMS proposes to use OPTN's organ offer acceptance rate ratio as the sole performance measure in the efficiency domain. This measure is calculated by dividing the number of kidney transplant organs accepted by each IOTA participant by the risk-adjusted number of expected organ offer acceptances. The measure uses logistic regression with risk adjustment for several characteristics, including donor quality and recipient characteristics; donor-candidate interactions, such as size and age differences; number of previous offers; and distance of potential recipient from the donor.

The AHA appreciates CMS' focus on encouraging the use of as many viable kidneys as possible, and CMS' proposed use of an existing risk-adjusted measure. **However, we oppose CMS' proposed approach to the efficiency domain because it is mismatched with other regulatory requirements for transplant hospitals, misaligned with the data used in the rest of the IOTA model, and may inadvertently serve to magnify rather than reduce transplant inequities.**

As CMS correctly notes in the proposed rule, the OPTN currently requires participating transplant centers to meet a minimum threshold of 0.30 on the organ offer acceptance ratio. As the AHA understands it, this measure was implemented in this fashion to identify performance outliers. The current approach also recognizes that the organ offer acceptance ratio is driven by multiple factors, some of which may not be fully within a transplant center's control or capturable in the risk adjustment model for the measure. Yet, for the IOTA model, CMS proposes a tournament model with this metric where hospitals are placed into quintiles of performance on the metric, awarding more points to those in higher performance percentiles. The AHA is concerned that this forced ranking may create artificial distinctions in performance — and award points differentially — in ways the measure was not designed to assess.

Furthermore, it appears that CMS would base percentile rankings on the performance of all hospitals performing kidney transplants and not just those participating in the IOTA model. Given that CMS is expressly proposing to apply differing incentives to IOTA hospitals, ranking their performance against hospitals not included in the model seems discordant.

However, the AHA's most significant concern about CMS' proposed use of the organ offer acceptance ratio measure is the potential for the measure to incentivize more conservative choices about which organs to accept. As a result, the measure could inadvertently run counter to CMS' goal of a greater number of transplants to patients who could benefit from them. By design, the organ offer acceptance measure includes only those organs that a transplant hospital ultimately accepts, not the entire universe of potentially available organs. Awarding a higher number of points based on the percentile of performance on the measure could inadvertently encourage hospitals to make the clinical criteria for which patients should be on a transplant list more stringent, thereby limiting the number of patients who could receive an organ. Organ access could be further hampered by OPO assessment on

organ offer acceptance rates. OPOs may have the incentive to bypass offering transplant centers a particular organ knowing that the center may be more inclined to conduct a deeper clinical assessment of whether the organ is an optimal match for any of the patients on their waiting list. At a minimum, if CMS were to proceed with this measure, we believe awarding full points for meeting the OPTN's minimum ratio would be more appropriate and less apt to driving more conservative approaches to transplantation.

Quality Domain. CMS proposes four measures to calculate performance in the IOTA quality domain — a post-discharge composite measure reflecting graft survival rates, a shared medical decision-making measure, colorectal cancer screening and a care transition composite measure.

Composite Graft Survival Rates. This proposed measure is defined as the cumulative number of functioning grafts divided by the cumulative number of all kidney transplants performed by the IOTA participant during the first and all subsequent performance years. CMS would rank IOTA hospitals against national performance inclusive of all eligible kidney transplant hospitals regardless of whether they are included in the IOTA model, awarding up to 10 points based on performance.

The AHA opposes CMS' proposed composite graft survival rate measure because it lacks risk adjustment and, like the organ offer acceptance ratio measure, could incentivize even more restrictive criteria for transplantation. The proposed measure is of CMS' creation, notwithstanding the fact that transplant centers already report a variety of post-transplant outcome measures to the OPTN. Furthermore, if CMS' goal is to encourage more beneficiaries to benefit from transplantation, a survival rate metric that lacks adjustment for the clinical risk factors that may influence outcomes could inadvertently serve to make transplant centers more conservative about placing patients onto the transplant list. This is especially true of those transplant centers that care for the most clinically complex patients.

CollaboRATE shared decision-making. This measure is intended to assess the degree to which IOTA participants try to inform the patient of his or her health issues, listen to patient priorities and incorporate them into a patient's care plan. Measure performance would be calculated using a three-item survey administered to patients once per year.

The AHA appreciates the underlying goal of this proposed measure, and in concept, agrees with the notion of using the measure as pay-for-reporting only for the first two years. Yet, there are numerous other challenges with the measure that raise serious questions about its suitability for this model. For example, it is unclear whether and how this measure has been validated for use in hospitals and among kidney transplant patients. Furthermore, the proposed rule lacks numerous important logistical details critical to understanding how hospitals would be expected to collect the measures and how CMS would score them. For example, CMS does not indicate what type of patient information it expects hospitals to collect and report along with the measure results, or

whether it expects the reporting of patient-level or aggregate data. While CMS proposes response rate threshold percentages, it fails to define what it means by "complete and accurate reporting" that would enable it to calculate this percentage, or even describe a numerator and denominator for data completeness thresholds. **Unless and until CMS can provide these additional details, the AHA cannot support the use of this measure in this model or any CMS program.**

Three-item Care Transition Measure (CTM-3). This patient-reported measure is based on a three-item questionnaire provided to patients after hospital discharge assessing whether patient and family preferences were included in the care plan, whether patients understand their role in self-management, and whether hospitals provide appropriate medication education. The CTM-3 is included in the current version of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey. However, as part of the fiscal year 2025 inpatient prospective payment system proposed rule, CMS proposed the removal of the CTM-3 for HCAHPS surveys on or after Jan. 1, 2025. Presuming CMS finalizes this proposal, IOTA participants would be required to report the CTM-3 separately from their HCAHPS surveys.

The AHA appreciates CMS' proposed use of a well-established quality measure that has been validated for use in hospitals. Yet, we are puzzled by CMS's decision to propose a measure that it intends to remove from the hospital Inpatient Quality Reporting Program (IQR) in favor of an updated set of HCAHPS care coordination items, making the collection of CTM-3 data potentially duplicative and redundant. Furthermore, like the CollaboRATE measure proposed above, CMS provides far too little detail on how hospitals would be expected to collect the measures and how CMS would score them. **If CMS proceeds with the IOTA model, we encourage the agency to consider using the new HCAHPS care coordination composite rather than the CTM-3 measure. If the agency still intends to use the CTM-3, then we ask that it provide additional details on how it would collect data and score performance.**

Colorectal cancer screening rates. This measure assesses the percentage of patients 50-75 years of age that have had guideline-concordant screening for colorectal cancer. CMS asserts that kidney transplant recipients are at higher risk of colon cancer due to long-term immunosuppression, making the use of this measure aligned with the agency's goal of better outcomes for transplant patients.

The AHA is not confident this measure aligns with the core intent of the IOTA model and encourages CMS to consider quality measures more directly aligned with kidney transplant care. Certainly, we recognize that the use of immunosuppressive drugs poses risks, one of which could be a heightened risk of colorectal cancers. Yet, as we understand it, the core intent of the IOTA model is to help reduce inequities in kidney transplantation and ensure more patients benefit from kidney transplantation. Furthermore, decisions around colorectal cancer screening often are managed by a patient's primary care provider in the ambulatory care setting rather than by hospitals. Lastly, like the CollaboRATE and CTM-3 measures, the proposed rule lacks important

details describing how hospitals would report the measure and how CMS would score them. Such detail would be critical if CMS were to proceed with the measure.

HEALTH EQUITY REQUIREMENTS

Health Equity Plan. **If CMS proceeds with the IOTA model against AHA's recommendation, then the AHA would support CMS' proposal to require IOTA participants to submit a health equity plan to CMS starting in performance year two**. Elements of the health equity plan would include identification of health disparities within the IOTA beneficiary population, health equity goals, intervention strategies and performance measures.

We also recommend that CMS allow hospitals participating in multiple CMMI models that require health equity plans to submit a single plan applicable to all models. Given the potential overlaps between CMMI models, hospitals likely would use similar approaches to stratifying their data, monitoring performance and engaging with their communities. If hospitals can describe how their plans are relevant to the CMMI models in which they participate, we believe a single plan would suffice and promote a coordinated approach to health equity.

Demographic and Health-related Social Need (HRSN) Data Reporting. In the proposed rule, CMS indicates that it considered but chose not to propose requirements for IOTA participants to report certain data on patient demographics such as race, ethnicity, gender orientation and sexual identity. CMS also considered proposing a requirement to screen participants for HRSNs and report aggregate data to CMS. The agency welcomes comments on whether it should require demographic and HRSN reporting in future program years.

If CMS proceeds with the IOTA model, the AHA urges CMS to ensure that any HRSN and demographic data requirements are carefully coordinated with other programs and fully subject to notice and comment rulemaking. With respect to HRSNs, we would be concerned that a separate requirement for IOTA participants would be duplicative with the existing CMS IQR measure assessing the percentages of inpatients screened for HRSNs.

With respect to demographic data, it is important to note that federal standards for race and ethnicity data collection are undergoing a significant overhaul. On March 28, the Office of Management and Budget (OMB) issued an updated Statistical Policy Directive 15 (SPD-15) that governs how federal agencies collect and use race and ethnicity data in their programs, the first update since 1997. OMB made several groundbreaking changes to the guidance such as consolidating race/ethnicity into a single question, adding a new category for Middle Eastern and North African individuals to identify themselves, and establishing new minimum and detailed categories for each race/ethnicity field. Federal agencies have been given until October 2025 to develop

their plans to comply with these new standards and until March 2029 to come into full compliance.

We would anticipate that like other agencies, CMS is undertaking a thoughtful and thorough review process to standardize its approaches to collecting race and ethnicity data across all its programs to bring them into compliance with the new guidelines. We are concerned that adopting race and ethnicity data collection too soon would rush what should be a measured and careful process. We also would be concerned with CMS adopting a set of requirements that could rapidly change as the rest of the agency's plan comes into place.

As a practical matter, we also believe there are numerous and complex issues that CMS would need to sort through for the reporting of race, ethnicity or other patient self-reported data, demographic or social drivers of health data. For example, some individuals prefer not to report their race or ethnicity to hospitals and health systems. Some patients also may not wish to share information about their sexual orientation, gender identity or their living situation. CMS would need to articulate an approach for honoring the choices of patients who may choose not to share these data while not penalizing hospitals for not reporting "complete" data.

PAYMENT

The proposed IOTA model would include incentive payments or penalties for Medicare fee-for-service (FFS) payments for kidney transplants. Participants would be measured against specified targets in achievement, efficiency and quality domains, and earn a score not to exceed 100 points (as described above). Hospitals would be eligible for incentive payments of up to $8,000 per case or penalties of up to $2,000 per case. **This proposed payment methodology is fundamentally flawed. For example, the inadequate incentive payment structure would penalize hospitals participating in the model, and effectively their patients, because it would siphon resources away from other clinical care areas.**

Incentive Payments Are not Sufficient to Cover Costs, While Downside Penalties Can Harm Programs. Aside from the unrealistic thresholds established under the performance score methodology, if a hospital were able to achieve a maximum performance score, it would still potentially not be able to cover costs and resources associated with the model. These costs and resources include, for example:

- Staff and software to track attributed populations and metric performance.
- Staff and software to support transparency requirements including maintenance of public websites for reporting of eligibility criteria and monthly notification to each beneficiary of organ declinations.
- Staff and software to support demographic and health-related social need data reporting.
- Staff to support health equity plans.

- Staff and space to support increased transplant volume. This may include additional transplant coordinators, clinical staff (including surgeons and nurses), and capital for additional operating room (OR) suites.

The proposed maximum payment of $8,000 per case would not cover the costs of these various requirements built into the model. **This inadequate bonus structure would therefore penalize all hospitals participating in the model, and effectively their patients, because it would siphon resources away from other clinical care areas.** This could also impact workflows for other clinical areas. Often multiple service lines utilize OR suites, which means that there is limited capacity to increase volumes without requiring additional space.

It is noteworthy that the proposed bonus is not comparable to other models like the KCC model (which had a $15,000 bonus, roughly equating to $18,000 today when accounting for inflation). Yet, the justification provided in the proposed rule for why this maximum payment was not pursued was that it would be too large to generate savings. **This statement illustrates the arbitrary nature of this model and the need to provide additional refinements before implementation.**

Meanwhile, the proposed penalties pose significant risks for hospital transplant programs. In addition to the increased costs outlined above, potential penalties mean that hospitals may be subject to an approximate 8% cut in payment per transplant. Many transplant programs would not be able to absorb these losses without reducing access to services. **Therefore, while CMS states that this model is intended to support increased access to organ transplants for underserved communities, the penalties mean that it may, in fact, *reduce* access for these same populations.**

This speaks to why the model should not be pursued. If CMS were to go ahead with implementation against AHA's recommendations, the payment methodologies must be updated to ensure that incentive payments would exceed the costs associated with implementing and maintaining the program. Model design features should also be established to ensure that downside risk would not adversely impact access. These features should include adequate risk adjustments and upside-only payments for certain provider types like safety net and rural providers.

<u>Timeline to Two-sided Risk Is Unreasonable.</u> The proposed IOTA model includes a one-year glidepath to two-sided risk. **If CMS does pursue IOTA implementation, a more gradual introduction of downside risk is necessary. Only one year of upside-only risk would not allow hospitals to learn from their first year in the model and adjust their approaches before moving into downside risk.** Indeed, hospitals would not know their first-year performance until six to nine months into their second year due to the proposed claims running out necessary for calculating performance. In other words, hospitals would be well into their second year and subject to six to nine months of downside risk while still unsure of their first-year performance. In addition, hospitals

need adequate time to prepare for downside risk, including time to incorporate adjustments to their practices as necessary.

MODEL OVERLAP

CMS proposes to allow overlap with IOTA and other CMS models including the KCC, End Stage Renal Disease Treatment Choices (ETC) Model and other APMs. The staffing and resources required for one hospital to stand up one APM, let alone multiple APMs, is challenging, particularly when or if they are being implemented at the same time. There is also the potential for organizations to be penalized in multiple models for the same cases and measures. A hospital could hypothetically be undergoing the transition to a hospital global budget under the States Advancing All-Payer Health Equity Approaches and Development model, required to participate in a mandatory bundled payment model under the TEAM, and supporting workflow changes from OPTN modernization all while being mandated to participate in IOTA. **Therefore, if CMS were to move forward with IOTA, hospitals participating in any other advanced APMs should be excluded from participating in IOTA.**

OVERLAP WITH DEPARTMENTAL REGULATORY EFFORTS

The Department of Health and Human Services (HHS) has issued other rules to support the transplant ecosystem, which includes outcome measures. For example, the Organ Procurement Organizations Conditions for Coverage was issued in 2020 and intended to increase donation and transplant rates by replacing outcome measures. OPTN also issued new measures in 2021 including a 90-day graft survival hazard ratio, a one-year conditional graft survival hazard ratio, a pre-transplant mortality rate ratio, and an offer acceptance ratio. **As outlined in more detail in the IOTA Performance Assessment section, CMS proposes measures not aligned with OPTN standards. This adds unnecessary complexity and administrative burden for tracking and reporting. Instead of pursuing unvalidated measures, metrics should be aligned with existing programs.**

FINANCIAL ARRANGEMENTS AND BENEFICIARY INCENTIVES

Fraud and Abuse Waiver and Office of Inspector General Safe Harbor Authority

If CMS moves forward with implementing the IOTA model, the AHA urges the secretary to use the full scope of the combined authority granted by Congress under Section 1115A(d)(1) of the Affordable Care Act to issue waivers of the potentially applicable fraud and abuse laws to enable participating hospitals to form the financial relationships necessary to succeed in the IOTA model before issuance of a final rule. Specifically, to the extent these arrangements are not already captured within the value-based care and CMS-sponsored payment model exceptions, the secretary should waive the Physician Self-Referral Law, the Anti-Kickback Statute and the Beneficiary Inducement

CMP Law (the “fraud and abuse laws”) with respect to financial arrangements formed by hospitals participating in IOTA that comply with the requirements in the proposed rule.

As proposed, any financial arrangement or agreement under the IOTA model that implicates fraud and abuse laws would not be protected unless it falls under an existing exception or safe harbor. Under IOTA, hospitals would bear responsibility for the financial and quality outcomes of other providers who provide care to Medicare beneficiaries during qualifying episodes. Although AHA takes the position that the value-based exceptions to the fraud and abuse laws and the CMS-sponsored model arrangement safe harbor to the Anti-Kickback Statute should cover many scenarios, it is critical that HHS fully mitigate the risk for hospitals, whose participation in this program would be mandatory. CMS itself acknowledges in the proposed rule that the financial relationships between hospitals and IOTA collaborators may implicate fraud and abuse laws. **Hospitals must have needed, explicit protections in place and adequate time to form the necessary financial arrangements. As the Administration is aware, such programs cannot be successful for Medicare and its beneficiaries without these protections.**

Collaborators

CMS proposes that several types of providers and suppliers that are Medicare-enrolled and eligible to participate in Medicare may be IOTA collaborators. **We would urge CMS to include the newly established Medicare provider type, the rural emergency hospital, as a collaborator if the agency were to move forward with this model. This would enable rural providers to better align their care delivery for model participants.**

Beneficiary Incentives

CMS recognizes that the cost of immunosuppressive drugs is a financial burden for many transplant recipients, particularly those without sufficient health insurance coverage. We appreciate the agency’s desire to waive cost-sharing for these beneficiaries. The agency proposes to allow IOTA participants to subsidize, in whole or in part, the cost-sharing associated with immunosuppressive drugs (ID) covered by Part B, the Part B-ID benefit and Part D incurred by attributed patients. However, the agency had also considered waiving Medicare payment requirements such that CMS would pay the full amount of the Part B or Part B-ID coinsurance for IDs that are medically necessary for preventing or treating the rejection of a transplanted organ or tissue. **If CMS moves forward with this model, we would urge it to waive Medicare payment requirements such that CMS would pay the full amount of coinsurance for these high-cost drugs, especially given the current financial challenges faced by hospitals and health systems.**

DATA SHARING AND TRANSPARENCY REQUIREMENTS

Beneficiary Claims

Model participants should have timely access to data about their patient populations. Historically, the lack of transparent, real-time data created confusion on trigger events, eligibility for episodes and program participation. CMS proposes to provide beneficiary claims data no later than one month after the start of each performance year, including three years of historical Parts A, B and D claims and monthly claims for attributed patients. Additionally, CMS proposes that it would share quarterly a beneficiary attribution report, which would include a list of attributed patients and patients who have been de-attributed from the IOTA participant. **If CMS moves forward with this model, the provision of these data points would be necessary. However, providing them after the start of performance is not sufficient. We urge the agency to convey this information at least 90 days before the beginning of the relevant performance year.**

Additionally, because the proposed performance score would be calculated regardless of payer, IOTA participants would need more than the proposed Parts A, B and D data to assess their performance. **If CMS moves forward with this model, we ask the agency to provide all necessary data, including but not limited to providing participants with all-payer OPTN data promptly so that they can assess their performance in the program.**

Records Retention

CMS proposes to replicate in IOTA audit and record retention requirements policies set forth in previous models. It also proposes that the federal government would have a right to audit, inspect, investigate and evaluate any documents and other evidence regarding the IOTA implementation, as with any other CMMI model. Additionally, to align with the policy of current models being tested by IOTA, CMS is proposing that the IOTA participant and its IOTA collaborators must maintain and give the federal government access to all documents and other evidence sufficient to enable the audit, evaluation, inspection or investigation. **If CMS moves forward with IOTA against AHA recommendations, we urge CMS to use HIPPA documentation retention standards rather than setting CMMI-specific standards.**

Transparency Requirements

CMS states that to improve transparency for those looking to gain access to a transplant waitlist, it is proposing to require IOTA participants to publicly post, on a website, their patient selection criteria for evaluating patients for addition to their kidney transplant waitlist by the end of performance year one. CMS also proposes to add requirements to increase transparency for IOTA waitlist patients who are Medicare beneficiaries regarding the volume of organ offers received on their behalf while on the waitlist. Specifically, CMS proposes that an IOTA participant must inform monthly IOTA

waitlist Medicare beneficiary patients of the number of times an organ is declined on the Medicare beneficiary's behalf and the reason(s) for the decline.

Under current Medicare CoPs, transplant hospitals already document the patient selection criteria on the patient's medical record and provide a copy and discuss these criteria with the patient. Hospital members also indicate that these criteria remain fairly consistent across the kidney transplant field and, as such, the proposal does not address the goal of "improving transparency" for those looking to be added to the waitlist when such information is readily available and already communicated to patients.

Additionally, transplant teams already have extensive discussions with the primary patient about the reasons for declining an organ on their behalf. Transplant teams use multiple criteria to determine whether an organ is suitable for transplant, including looking holistically at the organ viability (e.g., age, creatinine levels, blood pressure, anatomy), rather than determining transplantation on a single data point. The transplant hospital may choose to decline an organ for several waitlist patients based on its holistic assessment that the organ is simply not suitable writ large. Yet, under CMS' proposal, the transplant hospital would need to inform every waitlist patient of all the reasons every time an organ is declined. **This is a large administrative undertaking and has the potential to lead to significant confusion for patients.** Additionally, this can interfere with the provider patient relationship, where providers and patients jointly have a conversation about the appropriateness of organs.