



Charles N. Kahn III
President and CEO

July 16, 2024

Via electronic submission at <http://www.regulations.gov>

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

RE: Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model (CMS-5555-P)

Dear Administrator Brooks-LaSure:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, childrens', and cancer services.

We are writing in response to the recent Centers for Medicare & Medicaid Services' (CMS) and Center for Medicare and Medicaid Innovation (CMMI) Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model Proposed Rule. In this rule, CMMI under its 1115A waiver authority, proposes a new 6-year mandatory model that would test whether performance-based incentive payments or penalties for participating kidney transplant hospitals increase access to kidney transplants for patients with end-stage renal disease (ESRD). The IOTA Model would begin on January 1, 2025 and end on December 31, 2030, comprised of six performance years. Participation in the IOTA Model would be mandatory for 50 percent of all eligible kidney transplant hospitals in the United States. This would result in about 90 kidney transplant hospitals being selected to participate in the IOTA Model. CMMI

would measure and assess the participating kidney transplant hospitals' performance during each PY across three performance domains: achievement, efficiency, and quality. The organ transplant hospital's final performance score earned from each of these domains would determine whether it would be eligible to receive an upside risk payment from CMMI, fall into a neutral zone where no upside or downside risk payment would apply, or owe a downside risk payment to CMMI. The Proposed Rule also includes standard provisions that would be applicable to all CMMI Innovation Center models with a performance period that starts on or after January 1, 2025.

The FAH has serious concerns with key components of CMMI's IOTA Model and we strongly oppose the mandatory participation requirement of the proposal. Mandatory provider and supplier participation in CMMI models effectuates an impermissible mandatory change to the Medicare program and runs counter to both the letter and spirit of the law that established the CMMI. CMMI's demonstration authority is limited to testing models under section 1115A and the making of recommendations to Congress, but Congress reserved for itself the authority to make permanent or mandatory changes to the Medicare program and the IPPS through legislation. **Instead of a mandatory payment demonstration, we urge CMMI to ensure that all CMMI models are voluntary and designed to test—at an appropriate scale—alternative payment models.**

Beyond the mandatory participation approach, we are concerned that the IOTA Model as proposed is not ready for implementation – especially for the proposed start date of January 1, 2025. While we share CMMI's concern about health outcomes for patients with ESRD and we also would like to see more eligible patients receive life changing transplant care, the model inappropriately incentivizes exorbitant transplant program growth and participating hospitals would find it very challenging to succeed under the current design. We believe that very few participating hospitals would be able to perform at a level that would allow them to receive upside payment adjustments and that many participants would find that the new reporting and participation costs of making major program changes far outweigh the benefits of potential payment adjustments.

In addition, we are concerned that some of the incentives designed to address equity in access to transplantation may lead to lower success rates that could create different types of disparities in transplantation care. These challenges, combined with other major changes occurring in the transplantation ecosystem related to organ acquisition and allocation (i.e. Continuous Distribution), the Kidney Care Model, and impending action CMS will enact on low performing organ procurement organizations, could put too many changes on the transplant community to manage at the same time. Additionally, work currently underway by the OPTN Expedient Task Force in combination with these preceding efforts mentioned, could also confound analysis of program results. We recommend that CMMI push back implementation, work with stakeholders to address concerns related to downside risk and unachievable performance measures, develop program-specific quality measures for transplantation, and avoid any mandatory approaches in the future.

MANDATORY MODEL APPROACH

The FAH is concerned with the proposed national, mandatory demonstration of the IOTA Model and strongly opposes mandatory provider participation in any CMMI testing. The FAH has repeatedly expressed significant legal and policy concerns with mandatory CMMI models and has urged HHS to ensure that CMMI acts only within its designated authority to test voluntary alternative payment models. These objections to mandatory demonstrations are particularly acute with respect to the IOTA Model proposal in light of its extraordinarily wide proposed breadth—*half* of all eligible kidney transplant hospitals nationwide would be mandated to participate.

Mandatory provider and supplier participation in CMMI models effectuates an impermissible mandatory change to the Medicare program and runs counter to both the letter and spirit of the law that established the CMMI. CMMI’s demonstration authority is limited to testing models under section 1115A and the making of recommendations to Congress, but Congress reserved for itself the authority to make permanent or mandatory changes to the Medicare program and the IPPS through legislation.

The language, structure, intent, and requirements of section 1115A of the Social Security Act (SSA) clearly indicate that Congress did not delegate broad lawmaking authority to the Secretary and CMMI. Under section 1115A(a)(1), CMMI tests innovative payment and service delivery models to maintain or reduce program expenditures while preserving or enhancing quality of care, with an emphasis on models that improve coordination, quality, and efficiency of health care furnished to Medicare and Medicaid beneficiaries. The statute directs the Secretary to select “from models where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures.” SSA § 1115A(b)(2)(A). In subsection (c), the law further directs CMMI to evaluate each Phase I CMMI model, and only after taking into account this evaluation, if appropriate, the model may continue to be tested in Phase II to expand “the duration and the scope,” provided certain requirements are met, including a requirement for a separate notice and comment rulemaking for any expansion. Finally, CMMI is required to report periodically to Congress on CMMI models and provide *recommendations* for legislative action “to facilitate the development and expansion of successful payment models.” SSA § 1115A(g).

The statutory text thus broadly makes clear that CMMI models must be limited in scope and that Congress reserved for itself the authority to make mandatory changes in Medicare payment systems (*see* SSA § 1115A(g)). Nowhere does the law permit mandatory provider participation in the testing of CMMI models, which would eviscerate the IPPS and other payment systems mandated by statute.

CMMI nonetheless proposes to adopt the IOTA Model, a six-year “mandatory Medicare payment model to be tested under section 1115A of the Act” (89 Fed. Reg. at 43,518). Recent case law, however, confirms that CMMI’s assertion of authority under section 1115A to mandate a demonstration model is misplaced. To the extent that there is any ambiguity considering limitations on the testing authority under section 1115A of the Act, the Supreme Court recently confirmed that no deference is owed the Secretary’s interpretation of the statute. *See Loper*

Bright Enterprises v. Raimondo, 603 U.S. ___, No. 22–451 (2024) (overturning *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984)). Rather, it is the courts that are charged with “independently interpret[ing] the statute and effectuate the will of Congress subject to constitutional limits . . . by recognizing constitutional delegations, ‘fix[ing] the boundaries of [the] delegated authority,’ and ensuring the agency has engaged in ‘reasoned decision-making’ within those boundaries.” *Id.*, slip op. at *18 (citations omitted). This is particularly true “when the ambiguity is about the scope of an agency’s own power—perhaps the occasion on which abdication in favor of the agency is *least* appropriate.” *Id.* at *23. Thus, no deference is owed to the Secretary’s impermissibly broad interpretation that section 1115A of the Act permits him to implement broad payment changes on a mandatory basis under the guise of testing a model.

Moreover, in recent years, courts have continued to make clear that constitutional limits inform the scope of agency authority. In particular, grants of authority to agencies must be narrowly construed and delegations of broad authority should not be presumed to exist. For example, the Supreme Court has been explicit that agencies must have clear Congressional authorization to exercise extraordinary regulatory authority. *W. Virginia v. Env’t Prot. Agency*, 597 U.S. 697, 732 (2022). “Agencies have only those powers given to them by Congress, and ‘enabling legislation’ is generally not an ‘open book to which the agency [may] add pages and change the plot line.’” *Id.* at 723. As such, Congress does not typically use “modest words,” “vague terms,” “subtle devices,” or “oblique or elliptical language” to empower an agency to make a fundamental change to a statutory scheme. *Id.* (citing *Whitman v. American Trucking Assns., Inc.*, 531 U.S. 457, 468 (2001); *MCI Telecommunications Corp. v. American Telephone & Telegraph Co.*, 512 U.S. 218, 229 (1994)); see also *Biden v. Nebraska*, 143 S. Ct. 2355, 2372–75 (2023) (Congress did not provide “clear congressional authorization” for the Secretary to act in ways that would in effect fundamentally revise the statutory scheme).

Mandating provider participation in the IOTA Model (and other CMMI models) transforms the methodology through which providers receive Medicare payments from the statutorily mandated, predictable prospective payment system to one that requires, for *half* of the eligible kidney transplant hospitals nationally, assuming two-sided risk for kidney transplants. No such authorization exists or should be presumed to exist here—Congress has not included in the authorizing statute any statements indicating that it intended to and actually did delegate its lawmaking role to CMMI to require half of the nation’s eligible kidney transplant hospitals to accept this different, unpredictable payment scheme in lieu of full IPPS payments for these services. Rather, § 1115A(g) indicates Congress reserved the authority to adopt such fundamental alterations for itself.

Notably, were Congress to have clearly articulated such a broad delegation of authority to CMMI to alter the Medicare reimbursement scheme (again, it has not), it would need to provide intelligible principles defining the scope of its delegated authority to ensure such a delegation to the agency was constitutionally sound. This is especially true because Congress precluded administrative or judicial review of a substantial number of matters of CMMI demonstration authority under section 1115A(d)(2) to permit the testing of models.

The Proposed Rule briefly addresses a fully voluntary model as an alternative considered but concludes that a voluntary model “would not be evaluable, would result in insufficient numbers of kidney transplant hospital participants, and would not be representative of kidney transplant hospitals and ESRD patients nationally” (89 Fed. Reg. at 43,541). But section 1115A’s requirement that the Secretary evaluate its models (*see* SSA § 1115A(b)(4)), does not and cannot be read to authorize the Secretary to mandate participation in a demonstration project. *W. Virginia*, 597 U.S. at 723 (“Extraordinary grants of regulatory authority are rarely accomplished through modest words, vague terms, or subtle devices. Nor does Congress typically use oblique or elliptical language to empower an agency to make a radical or fundamental change to a statutory scheme.”) (internal quotations and citations omitted). Rather, CMMI may conduct appropriate voluntary testing and, if it has exhausted meaningful, voluntary testing and believes that an expansion to a mandatory model is appropriate, it may provide appropriate recommendations to *Congress* for “legislative action to facilitate the development and expansion of successful payment models.” SSA § 1115A(g).

In sum, CMMI’s proposal of the mandatory IOTA Model demonstration is an overreach of agency authority that contradicts the statutory mandate of section 1115A and raises concerns about impermissible delegation of lawmaking authority to the executive branch. These concerns are particularly acute considering the extraordinary breadth of the proposed demonstration: again, participation in the IOTA Model would be mandatory for 50 percent of all eligible kidney transplant hospitals in the United States. **Because section 1115A does not authorize mandatory payment demonstrations, we strongly oppose the implementation of the IOTA Model as proposed. Instead, we urge CMS to ensure that all CMMI models are voluntary and designed to test—at an appropriate scale—alternative payment models.**

REFINEMENTS TO THE IOTA MODEL

In addition to the FAH’s concern that CMMI does not have statutory authority to implement a mandatory model, we also have serious concerns about the design and incentives in the IOTA proposal and recommend improvements to address those concerns. We recommend that CMMI pause to consider these comments and those of other stakeholders before moving forward with this proposal.

CHANGES NEEDED TO OVERALL ALTERNATIVE PAYMENT DESIGN

Program Start Should Be Delayed and Performance-based Payment Model Should Provide Only Upside Risk Payments for the Duration of the Model

The FAH urges CMMI to reconsider the value of two-sided risk payment model for the IOTA participants to achieve the desired goals of the IOTA model. As CMMI acknowledges “while kidney transplant hospitals are subject to value-based payment programs, some IOTA participants may have limited APM experience, resources, and capacity to meet model goals.” **Instead, the FAH urges CMMI to adopt an upside-risk payment only framework that would still base model payments on kidney transplant utilization and other metrics of efficiency and quality.** The magnitude of the downside risk payment from the IOTA Model is relatively small and unnecessary to incentivize growth in the number of kidney transplants furnished to patients with ESRD.

If CMMI decides to maintain the two-sided risk framework, the FAH urges CMMI to delay the start of the program for at least one year and to phase-in of downside risk no sooner than PY 3. CMMI is proposing to begin performance year (PY) 1 of the IOTA model beginning January 1 2025. With publication of a final rule not even 6 months in advance of the start date, this overly impatient timeline ignores how much preparation that participating transplant hospitals will need to accomplish to meet the model goals. The timeframe does not provide enough time for planning, the addition of new staff that will be needed to ramp up program volumes, process changes, new reporting requirements, and other changes needed to successfully implement the program.

In addition, CMMI should delay the start of downside risk to no sooner than PY 3. The goals of this program as described by CMS are focused on improving the quality of life of ESRD patients and to increase the number of adults receiving kidney transplantation. Adding risk to the model and increasing the costs of offering a kidney transplantation program goes in the opposite direction of this goal.

MA Enrollees Receiving Kidney Transplants Should Be Included in Calculation of Model Performance-Based Payments

While CMMI proposes to assess model performance for each IOTA participant for all attributed patients regardless of payer type, CMMI proposes model performance-based payments that would only be based on kidney transplants furnished to attributed patients with Medicare FFS as the primary or secondary insurance. This would not include, for example, kidney transplants furnished to attributed patients enrolled in Medicare Advantage (MA), as kidney transplants are a Medicare-covered service that MA plans must also cover. CMMI states that to include MA in performance-based payment calculation, a potential waiver of section 1851(i)(2) of the Act, which provides that only the MA plan shall be entitled to payments for services furnished to the beneficiary, may be necessary to apply the payments to attributed patients enrolled in MA. CMMI states that waiving this requirement would be unprecedented and the effects are unknown.

The FAH urges CMMI to reconsider and revisit pursuing a waiver of section 1851(i)(2) of the Act to allow MA patients receiving kidney transplants at a participating IOTA hospital be included in the calculation of Model Performance-Based payments. We agree with CMMI's reasoning in the proposed rule that the benefits of applying model performance-based payments to transplants furnished to attributed patients enrolled in MA would recognize the growth in MA enrollment relative to Medicare FFS enrollment, strengthen the model test through aligned payment incentives across payers, and protect against unintended consequences of incentivizing inappropriate organ offer acceptance based on payer type. The IOTA Model also would have a much larger effect if transplant hospitals received performance-based payments based on their entire panel of attributed beneficiaries who receive transplants, and not just based on transplants for attributed beneficiaries with Medicare FFS as their primary or secondary insurance.

PERFORMANCE ASSESSMENT OF IOTA MODEL IS UNTESTED AND NEEDS REFINEMENT

Transplant target calculation for IOTA Model Needs Refinement

CMMI proposes that for each model PY, it would calculate a “transplant target” for each IOTA hospital, which would determine the achievement performance defined “as the target number of transplants set for each participant.” Transplants would include deceased donor and living donor kidney transplants furnished to patients 18 years of age or older. To calculate the transplant target, CMMI would determine the **highest** number of deceased donor kidney transplants and living donor kidney transplants during the three-year baseline period. CMMI would combine the deceased and living donor numbers even if they were achieved during different baseline years. It would then trend this number by the national growth rate of all kidney transplants (i.e., 18 years of age or older), if the rate is positive, to determine the transplant target for a given PY.

The FAH is concerned that CMMI’s proposed approach does not take into account the natural year-to-year variability in overall and living/deceased donor volume of transplants performed within a program. **We recommend an alternative approach that CMMI discussed in the proposed rule that would set each IOTA participant’s transplant target by determining the IOTA participant’s average total kidney transplant volume from the three previous years.** This three-year averaging approach, which is a common approach used by CMMI in other payment approaches, would smooth out year-to-year variation and potential outliers in a particular year for deceased and/or living donor transplants.¹ **Likewise, for similar reasons, the FAH recommends determining the national growth rate by calculating the average growth rate across multiple baseline years instead of the proposed approach of using two years prior to the PY to one year prior to the PY.** This overall approach of using multiple baseline years, as noted by CMMI, would be simpler and result in a transplant target that is potentially more attainable for IOTA participants, assuming that the average kidney transplant volume is lower than the sum of the highest volumes of deceased and living donor kidney transplants.

Proposed Methodology for Calculation of Achievement Domain Points is Flawed

CMMI proposes that the achievement domain would be worth 60 points (out of 100) in the calculation to determine whether and how much a transplant hospital receives as a performance-based payment. Under its proposal, an IOTA participant’s performance would be assessed relative to their transplant target with those performing at less than 75 percent of the target would receive no points and those performing at 150 percent of the target receiving 60 points (the maximum). Performance in between 75 and 150 percent of the transplant target may earn participants 15, 30, or 45 points in the achievement domain. CMMI notes that it chose 150

¹ For example, CMS use three-year average of the most recent available audited Worksheet S-10 data to calculate Factor 3 in the uncompensated care formula used to allocate funds to hospitals. Benefits cited included minimizing year-to-year volatility, ensuring stability in future uncompensated care payments, and mitigating the effects of irregular trends and data anomalies.

percent as the maximum performance level based on the theoretical capability of growth in one year and analysis in trends over time.

The FAH strongly disagrees with the achievement thresholds proposed by CMMI as we believe these are arbitrary and without any supporting evidence/analysis or detailed justification to support such aggressive transplant targets for the achievement domain.

This formula does not take into account the inability of transplant programs to scale up the volume of the number of transplants performed in a given year. While some programs may have some excess capacity and would be able to perform more transplants in a given year, others would have to incur substantial fixed costs to expand their programs beyond their current volume of transplants. Our member hospitals have also indicated that it would be difficult in this labor market to recruit and retain the highly specialized staff needed and transplant physicians to expand the capacity of their transplant program to achieve these aggressive targets. In addition, this growth would be required each year of the program – which means near exponential growth is needed over the 6-year program.

The table below provides an example of the growth needed by a transplant program that has been around 225 total kidney transplants per year from 2021 through 2024. For this hospital to achieve the full 60 points under CMS’ 150% target, it would need to grow by 58% in 2025, and by 289% in PY 6. The growth would expand their program from 226 in 2021 to 879 in 2030. This type of growth is highly unlikely and virtually unachievable by the vast majority of transplant programs – which means hospitals will view the incentive payments as unachievable. Setting up unrealistic expectations will make it difficult for transplant programs to take the model seriously and make significant program investments to maximize the IOTA model unlikely. While the table does not incorporate the additional points for uninsured transplant patients, it still shows how excessive growth would need to be.

Alternatively, the table also shows growth needed at a more realistic 110% growth target to achieve the full 60 points. A growth target of 110% offers an equally aspirational level that is much more attainable.

Sample Growth Table Showing Needed Volume to Gain Full 60 Points in Every Year of the IOTA Model for a Transplant Hospital											
	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	
Historic Volume of Transplant Hospital	226	225	220	224							
National growth factor (estimate assuming 5% growth increases per year)					5.0%	5.0%	5.0%	5.0%	5.0%	5.0%	
Year used to set Target Volume					2021	2022	2025	2026	2027	2028	
Target (highest level of past 3 years+growth factor)					237	236	274	273	317	315	
Volume Needed to get full 60 Points at 150% (CMS Proposed)					356	354	411	409	475	473	
Growth needed compared to 2021 at 150% (starting target for model)					58%	57%	82%	81%	110%	109%	
Volume Needed to get full 60 Points at 110% (FAH Recommendation)					261	260	301	300	348	347	
Growth needed compared to 2021 at 110% (starting target for model)					16%	15%	33%	33%	54%	53%	

Given these results and if CMMI chooses to move forward with the model, the FAH recommends CMMI use a volume growth trend that better recognizes the potential limits

of transplant programs to expand capacity in a more reliable, realistic, and safe manner. We believe having a transplant goal that is more achievable would also incentivize the growth CMMI is trying to achieve. Setting transplant targets too high could discourage transplant programs from growing their programs at all if the targets are unrealistic and not achievable. We recommend the following alternative for assessment of the achievement domain that would allow transplant programs to achieve the maximum 60 points for the achievement domain with equal or greater than 110% of the transplant target.

FAH Achievement Domain Transplant Target Recommendations			
Performance Relative to Transplant Target	Lower Bound Condition	Upper Bound Condition	Points Earned
110% of transplant target	Equals 110%	N/A	60
100% of transplant target	Equals 100%	Less than 110%	40
75% of transplant target	Equals 75%	Less than 100%	20
75% of transplant target	N/A	Less than 75%	0

In addition, the FAH agrees and supports CMMI’s proposal to include a health equity performance adjustment, a 1.2 multiplier, for calculating the overall number of transplants furnished to patients attributed to a participating kidney transplant hospital during a PY. This would be applied to those patients that meet the low-income population definition. We believe, however, that this should be a reward-only adjustment to the performance score in the achievement domain, and thus should not be considered relative to setting realistic and achievable transplant targets.

PROPOSED METHODOLOGY USED TO CALCULATE UPSIDE RISK PAYMENT SHOULD HAVE A LARGER MAXIMUM UPSIDE RISK PAYMENT

CMMI proposes to define “upside risk payment” as a lump sum payment that CMMI would make to an IOTA participant hospital if the IOTA hospital’s final performance score for a PY is greater than or equal to 60 points. The IOTA hospital would then qualify for an upside risk payment. The proposed upside risk payment calculation formula is as follows:

$$\text{Upside Risk Payment} = \$8,000 * ((\text{Final Performance Score} - 60)/40) * \text{Medicare Kidney Transplants}$$

Within the calculation formula, \$8,000 is a fixed, risk-based payment amount estimated to be about 33 percent of the average Medicare FFS kidney transplant MS-DRG cost. Medicare kidney transplants is the number of Medicare FFS kidney transplants furnished by the IOTA participant in a PY.² CMMI states that it believes this creates a strong financial incentive with significant earning opportunity for IOTA participants that meet or exceed model performance expectations.

²An attributed patient in the IOTA Model whose primary or secondary insurance is Medicare fee for service (FFS), as identified in Medicare FFS claims with MS-DRGs 008, 019, 650, 651, and 652.

Total scores of 60 and above would result in a maximum upside risk payment of \$8,000. A participant, however, would need a 100 final performance score to obtain the maximum \$8,000 upside risk payment for each applicable Medicare FFS kidney transplant. **The FAH strongly urges CMMI to increase the maximum upside risk payment and include the Medicare Advantage patients in the upside risk payment calculation.** Based on discussions with our member hospitals with transplant programs, a combined score of 75 across the 3 domains would be very hard to achieve and would represent “high” performance, based on how the domains are currently constructed.

The following illustrative example, shown in the table below, demonstrates, however, that even a kidney transplant hospital with a very good performance score, would receive a total upside risk payment that is not large enough to effectuate real change. This example assumes that about 30 percent of the transplant volume is Medicare FFS – not unrealistic given that MA beneficiaries currently represent approximately 50 percent of Medicare ESRD beneficiaries receiving transplants. Other payers include commercial payers and Medicaid. Based on a final performance score of 75 points and the other stated assumptions, a kidney transplant hospital would receive a total upside risk payment of \$135,000. Based on the formula, the upside risk payment for each Medicare FFS transplants would be \$3,000.

Illustrative Example of Total Upside Risk Payment for a Participating Kidney Transplant Hospital Based on Varying Final Performance Scores					
Transplant Volume	Final Performance Score	% of Medicare FFS Patients	Multiplier Final Performance Score (60/40)	Upside Risk Payment (\$8,000*Multiplier)	Total Upside Risk Payment*
150	60	30%	0	\$0	\$0
150	75	30%	0.375	\$3,000	\$135,000
150	90	30%	0.75	\$6,000	\$270,000
150	100	30%	1	\$8,000	\$360,000

(* Total Upside Risk Payment = transplant volume * % of MA * upside risk payment)

The level of financial incentive is not large enough to promote behavior changes, as CMMI argues in the proposed rule, and is unlikely to even cover the costs of one additional transplant RN coordinator. Our members’ transplant hospitals indicate that while these incentive payments would be helpful, the size of such payments are unlikely to offset the costs of system level resources and intervention needed to meaningfully increase the number of kidney transplants performed for Medicare beneficiaries. **To expand the current operational capacity of hospital’s transplant programs, the FAH strongly recommends CMMI increase the total upside risk payment that could be obtained by a participating transplant hospital by substantially increasing the size of the upside risk payment from \$8,000 and including MA patients in the upside risk payment calculation.** Specifically for the upside risk payment, the FAH encourages CMMI to base the maximum positive multiplier per Medicare kidney transplant claim based on the Kidney Transplant Bonus in the Kidney Care Choices (KCC Model). Adjusted for inflation, this Kidney Transplant Bonus would be roughly \$18,000 (\$15,000 in 2019), which would be the maximum allowable positive bonus payment per transplant.

MEDICARE COST REPORT IMPACT (ORGAN ACQUISITION COSTS)

The proposed IOTA model will result in a significant administrative burden to transplant hospitals as well as a material increase in costs as a direct result of their participation in the new CMMI alternate payment model. The current Medicare payment regulation at 42 CFR §413.402 Organ acquisition cost states, "...there are administrative and general costs that may be allowable and included on the cost report for an OPO or a TH." Irrespective as to whether the IOTA program remains mandatory or becomes voluntary, the FAH strongly recommends CMS update the definition of "cost related to organic acquisition" to specifically include:

- Cost associated with participation in the CMMI alternate payment Increasing Organ Transplant Access (IOTA) model including penalties incurred as a result of participation in the IOTA model.

QUALITY DOMAIN

CMS proposes to define the quality domain as the performance assessment category that assesses the IOTA participant's performance using measures that focus on improving the quality of transplant care by improving post-transplant outcomes and incentivizing increased kidney transplant volume. CMS proposes to include one post-transplant outcome measure, the composite graft survival rate, and a quality measure set that includes two patient-reported outcome-based performance measures (PRO-PM), the CollaboRATE Shared Decision-Making Score and the 3-Item Care Transition Measure and one process measure, the Colorectal Cancer Screening measure. CMS proposes that performance for the quality domain would be up to 20 points.

The FAH encourages CMS to use only those measures that are aligned with clinical evidence and vetted with clinical experts, tested to ensure that each produces reliable and valid results in the intended settings and level of analysis, and includes risk adjustment if appropriate. These measures should also seek and maintain endorsement by the Consensus-Based Entity (CBE). In addition, as CMS indicated, for several of the measures included in this domain, there is a risk of small case minimums, which could negatively impact the reliability of the measure. Carrying forward performance across six years to address this concern is not useful and could unnecessarily penalize a hospital for a year of poor outcomes, particularly when the measure is not risk adjusted for clinical and social risk factors.

Post-Transplant Outcomes:

The FAH is concerned that CMS proposes a new measure instead of using measures that have been risk-adjusted, validated, and incorporated into the Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR). Instead, as previously described, the FAH encourages CMS to use measures that are aligned with clinical evidence and vetted with clinical experts, tested for reliability and validity in the intended settings, and include risk adjustment when appropriate. These measures should also seek and maintain endorsement by the Consensus-Based Entity (CBE).

The proposed unadjusted rolling composite graft survival rate does not meet any of the above principles and we are extremely concerned that it would be used to determine fifty percent of a hospital's quality domain performance but not reflect the actual quality of care delivered. As mentioned for several of the measures included in this domain, there is a risk of small case minimums, which could negatively impact the reliability of the measure. Carrying forward performance across six years to address this concern is not useful and could unnecessarily penalize a hospital for a year of poor outcomes, particularly when the measure is not risk adjusted for clinical and social risk factors.

Requiring a measure not part of the OPTN and SRTR also causes comparison between hospitals required to participate in the IOTA and hospitals not selected as IOTA participants. The FAH believes it is important to have one standard post-transplant outcomes measurement set and it should be established by the organizations most experienced with kidney transplants and have the responsibility for ongoing evaluation of organ transplantations.

IOTA Quality Measure Set Is Not Fit for Purpose

CMS proposes to have hospitals report on three measures: CollaboRATE Shared Decision-Making Score (CBE ID: 3227), Colorectal Cancer Screening (COL) (CBE ID: 0034), and 3-Item Care Transition Measure (CTM-3) (CBE ID: 0228) and FAH has concerns with each of them.

The CollaboRATE Shared Decision-Making Score (CBE ID: 3227) Is Not Fit for Inpatient Care At This Time

The CollaboRATE measure was last reviewed for endorsement in 2019 and the FAH was unable to find any recent information on how the measure is used or how it currently performs. Based on the previous endorsement review, the measure is only tested for ambulatory group/practice, and it does not appear to have been expanded to the inpatient setting. The FAH questions why this measure would be appropriate for hospitals to report. In addition, testing showed that the measure only achieved a median reliability of 0.7 for 200+ patients. It is also not clear how the measure would be implemented in the inpatient setting or with this population specifically. Given the concerns regarding small numbers stated throughout the quality domain section, we do not believe that the measure will provide accurate reflections of the quality of care delivered to patients receiving a kidney transplant.

Colorectal Cancer Screening (COL) (CBE ID: 0034)

While we agree that colorectal cancer screening is an important quality topic, we question why this measure is the most relevant to patients receiving a kidney transplant and why a kidney transplant program should assume the responsibility for the screening. The measure was not designed to capture the quality of care delivered within the inpatient setting and we believe that hospitals may not be able to ensure that patients receive this screening within the reporting year, particularly if it is applied to patients' post-transplant. For example, if a patient receives the new kidney in the last quarter of the year, hospitals will not have sufficient time to ensure that patients receive the screening. CMS must carefully consider whether this measure can be feasibly implemented for IOTA hospitals and whether it could misrepresent the quality of care provided to patients due to imprecise specifications. In addition, this measure more

appropriately reflects the care provided by the patient’s primary care physicians who are an important member of the patient’s post-transplant care.

3-Item Care Transition Measure (CTM-3) (CBE ID: 0228)

The FAH does not support the inclusion of CTM-3 in the quality domain. The recent 2025 IPPS proposed rule plans to remove the CTM-3 questions and replace them with an updated Care Coordination sub-measure beginning in calendar year 2025. As a result, hospitals reporting on HCAHPS will be using different sub measures to evaluate care coordination and hospitals participating in the IOTA Model would not be asked to collect the newer questions that have been determined to better reflect patients’ perspectives. We do not agree with inclusion of an additional measure that will produce different results and introduce additional reporting burden since hospitals would need to administer a separate survey.

Calculation of Points for Quality Measure Set

While we appreciate the recognition that hospitals will need sufficient time to begin reporting on these measures and support the proposal that the first two years would be pay for reporting, we are concerned with the proposed response rate thresholds. We believe that they are unreasonably high, particularly since two of the measures are patient-reported and require the administration of a survey. It is well known that hospitals and others struggle to achieve response rates greater than 30% and as a result, we do not believe that assigning points based on how well a hospital can get patients to respond to a survey is an accurate reflection of quality. The rationale given for these high thresholds is to ensure adequate numbers, but we believe that CMS should identify alternative ways to address this issue rather than set requirements that are likely to be incredibly difficult to achieve.

PROPOSED REVISIONS TO 42 C.F.R. 512, SUBPART A AND GOVERNING DOCUMENTATION

The FAH is also concerned with the proposed revisions to 42 C.F.R. Part 512, Subpart A, which would inappropriately permit CMMI to determine the applicability of subpart A to demonstrations without notice-and-comment rulemaking. The proposed revisions to 42 C.F.R. § 512.100 would remove the current limitation that Subpart A is only applicable to the Radiation Oncology Model and the ESRD Treatment Choices Model and instead provide that the applicability of Subpart A is determined by each Innovation Center model’s governing documentation. “Governing documentation” would in turn be defined in revised 42 C.F.R. 512.110 as including documents not adopted through notice-and-comment rulemaking (*i.e.*, “the model-specific participation agreement, cooperative agreement, and any addendum to an existing contract with CMMI”). By statute, however, the Secretary is only permitted to take such action through notice-and-comment rulemaking. SSA § 1871(b); *Azar v. Allina Health Svcs.*, 587 U.S. 566 (2019).

This approach to expanding Subpart A’s applicability is also problematic in light of other recent demonstration model proposals. For example, the Proposed Rule gives no indication as to whether revised Subpart A would apply to the recently proposed Transforming Episode Accountability Model (TEAM) demonstration if both are finalized. As proposed, the TEAM

demonstration would not be subject to the provisions of existing Subpart A and would instead be subject to TEAM-specific regulations covering similar subject matters (*see* 89 Fed. Reg. 35,934, 36,548 (proposed 42 C.F.R. § 512.561), and 36,555 (proposed 42 C.F.R. §§ 512.582 through 512.596). To the extent that CMS intends proposed Subpart A to apply to the proposed TEAM demonstration in lieu of these proposed TEAM regulations, this should be stated explicitly in the proposed revisions to Subpart A along with an explanation of the differences between proposed Subpart A and the corresponding TEAM-specific provisions in proposed 42 C.F.R. §§ 512.561, 512.582–512.596. Based on the current proposal, it is unclear whether and to what extent CMS is proposing to modify the substance of its corresponding, proposed TEAM regulations, and in the absence of such discussion, stakeholders are deprived of any opportunity to meaningfully engage on the issue. Further, it is particularly inappropriate to propose that the question of the applicability of Subpart A would be resolved in “governing documentation” that includes materials not adopted through notice-and-comment rulemaking.

The FAH is also generally concerned with the proposed use of “governing documentation” not adopted through notice-and-comment rulemaking to determine other rights and obligations under the demonstrations. For example, proposed 42 C.F.R. § 512.190 suggests that the availability of reconsideration may be precluded by “the governing documentation for the Innovation Center model,” which could include participation or cooperative agreements and addenda to CMS contracts. The FAH strongly objects to any attempt to limit model participants’ reconsideration rights without notice-and-comment rulemaking.

To address these concerns, the FAH therefore urges CMS to change the definition of “governing documentation” in proposed 42 C.F.R. § 512.110 to only reference “the applicable Federal regulations that specify the terms of the Innovation Center model.” Moreover, to the extent that CMS intends to modify its proposed TEAM regulations by implication with this rulemaking, the FAH believes CMS is prohibited from doing so in this manner and must instead explain the proposed changes to the TEAM proposal and provide an opportunity for public comment on those changes.

* * *

The FAH appreciates the opportunity to offer these insights. We are committed to working with CMS to improve value and access to care for America’s seniors – and the care to ESRD patients that can benefit from kidney transplantation. If you have any questions or would like to discuss our comments in detail, please do not hesitate to contact me or a member of my staff at (202) 624-1534.

Sincerely,

