WISCONSIN INSTITUTE
FOR LAW & LIBERTY

July 11, 2024

RE: Public Comment on Centers for Medicare & Medicaid Services Proposed Rule, "Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model," Docket Number CMS-5535-P (May 17, 2024)

To Whom it May Concern,

The Wisconsin Institute for Law & Liberty (WILL) is a non-profit, public interest law and policy organization dedicated to advancing the rule of law, individual liberty, constitutional government, and a robust civil society. Through litigation, education, and public discourse, WILL's nationwide Equality Under the Law Project opposes discriminatory programs and policies that would prioritize characteristics such as race in decision-making over fairness, equality, and quality outcomes.

WILL submits this comment to raise significant constitutional and legal concerns about the Increasing Organ Transplant Access Model ("IOTA Model" or "Model") as set forth by the Centers for Medicare & Medicaid Services ("CMS") in its recently proposed rule.

At a high level, this proposed rule seeks to pilot a scoring system that would inform Medicare payments to (or from) kidney transplant hospitals. This Model imposes new requirements and expectations upon participating transplant hospitals in hopes of evaluating whether this system achieves increased access to kidney transplants and care and reduces disparities.

However, troublingly, the proposed rule is motivated, *at least* in part, by an unconstitutional, discriminatory purpose to achieve racially balanced outcomes in kidney transplantation.[1] More specifically, this proposed rule—especially through the "health equity plan" ("HEP") requirement—would implement and incentivize a system of racially discriminatory prioritization in organ transplantation access and services in violation of numerous, longstanding prohibitions forbidding the government and private entities from in engaging in racial discrimination.

I. The proposed rule is racially motivated and implements a race-based prioritization in kidney transplantation to address societal disparities.

As explained in the "Rationale for the Proposed IOTA Model" and throughout the proposed rule, the Model aims to "address disparities," and in particular, purported racial disparities given the extensive discussion on race and racial comparisons, including "the

[1] *See, e.g.*, *Vill. of Arlington Heights v. Metro. Hous. Dev. Corp.*, 429 U.S. 252, 265–66 (1977); *Students for Fair Admissions, Inc. v. President & Fellows of Harvard Coll. ("SFFA")*, 600 U.S. 181, 223 (2023).

numerous … studies regarding disparities in organ transplantation and organ donation that are cited throughout this proposed rule."[2]

In addition, further underscoring the proposed rule's focus on addressing racial disparities are the Model's goals to "[a]lign[] [w]ith [f]ederal [g]overnment [i]nitiatives and [p]riorities," "[p]romote equitable access to transplants," and "ensure that our model reaches ESRD patients residing in underserved communities."[3] For example, in seeking to implement "alignment" with the federal government, the agency defines "underserved communities" in terms of racial equity, drawing from Executive Order 13985 (Advancing Racial Equity and Support for Underserved Communities Through the Federal Government). Accordingly, under the proposed rule, the targeted "underserved communities" that the IOTA Model is purposed to "reach" include groups broadly designated by race—"Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color" categorically assumed to "have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life."[4]

The agency's proposal is replete with other examples similarly demonstrating that the proposed rule advances the federal government's desire to prioritize race in kidney transplantation and furthers existing initiatives developed with similar motives in mind.[5] Likewise, the agency's leadership has also confirmed the race-based motivations underlying the proposed rule. As Health and Human Services ("HHS") Secretary, Xavier Becerra, stated:

> The organ transplant industry, like every other part of society, is not immune to racial inequities. Black Americans disproportionately struggle with life-threatening kidney disease, yet they receive a smaller percentage of kidney transplants. The Biden-Harris Administration is taking concrete

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[2] *E.g.*, 89 Fed. Reg. 43518, 43530, 43533–35, 43579 (May 17, 2024), available at https://www.federalregister.gov /documents/ 2024/05/17/2024-09989/medicare-program-alternative-payment-model-updates-and-the-increasing-organ-transplant-access-iota.

[3] 89 Fed. Reg. at 43530–31, 43541.

[4] *Id.* at 43618; Executive Order 13985, §§ 2.(a) & (b) (Jan. 20, 2021), available at https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.

[5] *See, e.g.*, 89 Fed. Reg. at 43528–29, 43534 (explaining other regulatory schemes and alignment initiatives "to advance health equity" and reduce racial disparities, including the race-conscious Kidney Allocation System of 2014 and executive orders targeting racial equity, such as E.O. 13995 (Jan. 21, 2021) on Ensuring an Equitable Pandemic Response and Recovery, which established a health equity task force to "take swift action to prevent and remedy" racial disparities in COVID-19 care and outcomes).

> steps to remove racial bias when calculating wait times and rooting out profiteering and inequity in the transplant process.[6]

Worse yet, the HEP requirement further exemplifies and compounds the proposed rule's prioritization of race in the kidney transplantation process. The goal of the HEP requirement is "[t]o reduce disparities and promote health equity."[7] As such, IOTA Model participants must "identify health disparities within [their patient population] and outline a course of action to address them."[8] The HEP must be "approve[d]" by CMS, and the penalties for non-compliance are substantial, including recoupment of reimbursed payments for transplants, termination from the Model, and termination from the ability to receive reimbursement for other Medicare-reimbursed services required for transplantation, among many other potentially significant remedial actions.[9]

However, despite these serious consequences, the proposed rule provides *no* clear guidance on what precisely the HEP must assess, what it must improve, or how it must do so.[10] Instead, the significant discussion on purported racial disparities frames the basis for the proposed rule and is left to form expectations regarding the HEP requirement.

To be sure, following one such discussion of racial disparities, CMS confirms that the HEP "design feature is aimed at" reducing "barriers to care" that are "compounded by racial, socioeconomic and neighborhood factors."[11] Through the HEP "design feature," the agency seeks to implement "a unified framework of *interventions to address the distinct social contexts underlying differences among racial groups* in … kidney transplantation" under the "belie[f]" that targeting the "underlying" factors of racial disparities "may result in the desired outcomes of greater overall kidney transplant numbers and equity."[12] In other words, one purpose of the proposed rule and the HEP requirement is to remedy racial disparities in kidney transplantation by working backwards from these

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[6] U.S. Department of Health and Human Services, *Biden-Harris Administration Acts to Improve Access to Kidney Transplants* (May 8, 2024), available at https://www.hhs.gov/about/news/2024/05/08/biden-harris-administration-acts-improve-access-kidney-transplants.html.

[7] 89 Fed. Reg. at 43535.

[8] *Id.* at 43521.

[9] *Id.* at 43582, 43600–01.

[10] For example, the HEP "must" "[i]dentify target health disparities" and "[d]escribe the health equity plan intervention." *Id.* at 43582. But in defining the meanings and legitimate expectations of these terms, CMS mainly proposes to restate the terms: "We propose to define 'target health disparities' as health disparities experienced by one or more communities within the IOTA participant's [patient] population … that the IOTA participant would aim to reduce." "We propose to define "health equity plan intervention" as the initiative(s) the IOTA participant would create and implement to reduce target health disparities." *Id.*

[11] 89 Fed. Reg. at 43535.

[12] *Id.* (emphasis added).

"differences among racial groups" to address the "underlying" factors that will, in turn, alleviate purported racial disparities.

The agency's focus on racial disparities and goal "[t]o reduce [them] and promote health equity,"[13] coupled with the agency's lack of clear standards for the HEP strongly indicate that the mandated HEP can, and even should, identify racial disparities and implement a plan to address them—whether by direct race-based interventions or by those that are proxies for race-based interventions. At best, the proposed approach creates a high risk for the implementation of HEPs that advance the agency's racially discriminatory goals and employ racially discriminatory considerations against kidney transplant candidates and potential, or would be, kidney transplant candidates and recipients.

The agency's *brief* and *singular* mention of anti-discrimination provisions when discussing the HEP does *not* allay these concerns in view of the voluminous record focusing extensively on racial disparities in support of the proposed rule, including "numerous" racial disparity studies discussed throughout.[14] Ultimately, race is a priority under the IOTA Model and frames the basis and expectations for the HEP requirement.

II. The proposed rule runs afoul of the Constitution and other laws.

CMS and HHS (as government entities) and transplant hospitals participating in the IOTA Model (as private entities and federal funding recipients) are subject to numerous anti-discrimination laws—all of which forbid them from engaging in discrimination on the basis of race, color, ethnicity, and national origin. Among this panoply of prohibitions is the Equal Protection guarantee of the Fifth Amendment to the United States Constitution, which bars government-imposed discrimination on the basis of race. Meanwhile, myriad prohibitions prohibit private hospitals and providers from discriminating on the basis of race in healthcare—among them, Section 1557 of the Affordable Care Act, Title VI of the Civil Rights Act of 1964, the Civil Rights Act of 1866, and countless provisions under state and other federal statutory schemes.[15]

The United States Supreme Court recently reiterated the anti-discrimination standards of the equal protection guarantee and Title VI: "we have repeatedly explained,

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[13] *Id.*

[14] *Id.* at 43579, 43582.

[15] Under Section 1557 of the Affordable Care Act, patients may not be discriminated against based on race in "any health program or activity, any part of which is receiving Federal financial assistance." 42 U.S.C. § 18116. Likewise, Title VI of the Civil Rights Act of 1964 contains a similar prohibition. *See* 42 U.S.C. § 2000d. In addition, numerous other legal authorities—regulations, manuals, civil rights clearances, claim forms, and provider agreements, just to name a few—require certification or a formal attestation of compliance with non-discrimination laws, such as when submitting claims for reimbursement to federal programs. Further, private healthcare providers are subject to the Civil Rights Act of 1866, which prohibits race discrimination in contractual relationships and prevents private parties from conspiring to interfere with the civil rights of others. *See* 42 U.S.C. §§ 1981 & 1985. Finally, numerous statutory schemes under state law prohibit race discrimination.

... that the Government must treat citizens as individuals, not as simply components of a racial … or national class."[16] That is because "[d]istinctions between citizens solely because of their ancestry are by their very nature odious to a free people whose institutions are founded upon the doctrine of equality."[17]

Consequently, the government may not implement race-based preferences; nor may the government rest its actions upon any racially discriminatory purpose or intention—whether in whole or in part.[18] The Court's "forceful[] reject[ion] [of] the notion that government actors may intentionally allocate [racial] preference[s]" is especially critical where, as here, the nation's preeminent healthcare agency proposes to regulate access to lifesaving medical treatment and care for a racial purpose—essentially, to achieve racially balanced outcomes.[19]

Here, the IOTA Model is based, *at least* in part, on an impermissible governmental desire to ameliorate certain racial disparities in kidney transplantation access and outcomes. Moreover, the agency proposes to translate this racial purpose into racial prioritization through the HEP requirement in accordance with other federal directives and initiatives that similarly prioritize race. In fact, addressing the "underlying differences among racial groups" is the very basis of the HEP "design feature," requiring IOTA Model participants to "target health disparities" and implement "interventions" to address them.[20]

However, "government actors may not provide or withhold services based on race or ethnicity as a response to generalized discrimination or as a convenient or rough proxy for another trait that the government believes to be 'characteristic' of a racial or ethnic group."[21] Indeed, it is well-established that government entities and federal funding recipients may not advance racially motivated action to remedy general disparities in society.[22] Such "racial balancing" has been long held to be "patently unconstitutional."[23]

The proposed rule's focus on reducing generalized racial disparities indicates an impermissible racial purpose, and the ambiguous HEP requirement further nurtures—

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[16] *SFFA*, 600 U.S. at 223 & n.2 (evaluating a Title VI race discrimination claim "under the standards of the Equal Protection Clause" because "[w]e have explained that discrimination that violates the Equal Protection Clause of the Fourteenth Amendment committed by an institution that accepts federal funds also constitutes a violation of Title VI.") (citing cases).

[17] *Id.* at 208 (citing cases).

[18] *Arlington Heights*, 429 U.S. at 265–68.

[19] *See SFFA*, 600 U.S. at 220, 223.

[20] 89 Fed. Reg. at 43535, 43582.

[21] *Roberts v. McDonald*, 600 U.S. ---- (2023) (statement of Alito, J., respecting the denial of cert.).

[22] *SFFA*, 600 U.S. at 226; *Arlington Heights*, 429 U.S. at 265–268; *Rice v. Cayetano*, 528 U.S. 495 (2000).

[23] *SFFA*, 600 U.S. at 223.

if not outright instructs—participants to prioritize race through interventions that would remedy these societal disparities. Any race-neutral interventions aimed at "address[ing] the distinct social contexts underlying differences among racial groups" fare no better than explicitly race-based interventions because here, such "underlying" factors are simply being used as proxies for race—means to a racially discriminatory end.

To be sure, the proposed rule and its relied upon studies repeatedly explain the goal: "the need to focus on social determinants of health to reduce racial disparity."[24] But these interventions—whether carried out by the federal government or passed off to third party funding recipients—are fixed in a racial purpose devoted to targeting and ameliorating societal disparities on the basis of race and are, accordingly, illegal. Such racial discrimination is barred by the Constitution, and beyond the numerous anti-discrimination laws applicable to private healthcare entities, "it is also axiomatic that a [government] may not induce, encourage or promote private persons to accomplish what it is constitutionally forbidden to accomplish."[25]

At bottom, the agency's notion and goal to fix broad racial disparities violates the "twin commands" of equal protection because it rests on "pernicious stereotyp[ing]" that "demeans the dignity and worth of a person to be judged by ancestry instead of by his or her own merit and essential qualities" and implements this racial stereotype as "negative" to exclude individuals of disfavored racial classes.[26] Indeed, "it is not even theoretically possible to 'help' a certain racial group without causing harm to members of other racial groups."[27] Like college admissions, the proposed rule's goal to remedy broad racial disparities in organ transplantation is "zero-sum": the government cannot grant a benefit to one racial group without "discriminat[ing] *against* those racial groups that were not the beneficiaries of the race-based preference."[28, 29] This manner of racial stereotyping and exclusion against critically-ill patients is not only unconstitutional but also arbitrary and capricious.

What's more, at first blush, the agency's proposed scheme immediately fails to display the hallmarks of narrow tailoring required for racially motivated action. Among other significant failures, the targeted racial groups are "imprecise," "arbitrary," "undefined,"

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[24] *See, e.g.*, 89 Fed. Reg. at 43534–35, 43579 (citing Yue-Harn Ng et al., *Does Racial Disparity in Kidney Transplant Waitlisting Persist After Accounting for Social Determinants of Health*, Transplantation 104(7): 1445–1455 (July 2020)), available at: https://journals.lww.com/transplantjournal/fulltext/2020/07000/does_racial_disparity_in_kidney_transplant.25.aspx.

[25] *Norwood v. Harrison*, 413 U.S. 455, 465 (1973).

[26] *SFFA*, 600 U.S. at 218, 220.

[27] *Id.* at 271 (Thomas, J., concurring).

[28] *Id.* at 212, 218–19 (emphasis in original).

[29] Consequently, the agency's claim that a racially discriminatory approach to healthcare can "substantially increase the number of kidney transplants in a way that enhances fairness for all" is also remarkably disingenuous. *See* 89 Fed. Reg. at 43531.

"overbroad," and "underinclusive."[30] Although the proposed rule discusses at length purported disparities among racial classifications, the agency does not indicate what precisely it means by these categories; nor why some racial groups are prioritized over others (including prioritization over other racial minorities).[31]

The proposed scheme also lacks any "logical endpoint"—a "critical" limitation imposed by narrow tailoring. [32] In fact, far to the contrary, the proposed rule seeks to *expand* race-based considerations in kidney transplantation. As the proposed rule explains, the 2014 Kidney Allocation System (KAS), an earlier race-conscious program, is already at work achieving its "aim[] to lessen the impact of racial differences on access to kidney transplantation."[33] The agency acknowledges evidence pointing to a narrowing of racial disparities in transplant allocation following this systematic prioritization of certain races over others.[34] At ten years and running, it would defy all logic to contend that the agency's proposal to further expand race-conscious considerations in kidney transplantation is, or has been, in any way "temporary" or "limited."[35] Additionally, this expansion further underscores an impermissible governmental goal to achieve racially balanced outcomes.

As if all this were not enough, the agency's proposal to remedy general racial disparities is arbitrary and capricious for other reasons as well. On one hand, the agency indicates that the "social determinants of health (SDOH) may substantially explain racial disparities in both deceased and living donor kidney transplantation."[36] These determinants broadly include "those conditions in the places where people live, learn, work, and play that affect a wide range of health and quality of life risks and outcomes" such as "employment, neighborhood factors, education, social support systems, and healthcare coverage."[37] In other words, the agency acknowledges that purported racial disparities begin to dissipate when adequate factor control is properly employed. Yet, as

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[30] *SFFA*, 600 U.S. at 216.

[31] The federal government routinely excludes individuals from North Africa, the Middle East, and North Asia from the definition of "minority." *See Vitolo v. Guzman*, 999 F.3d 353, 358, 363–64 (6th Cir. 2021). The proposed rule also does not address whether Jews are included or excluded from special prioritization. Some agencies treat Hasidic Jews differently than other Jewish groups; the proposed rule does not address this issue. *See Nuziard v. Minority Bus. Dev. Agency*, --- F. Supp. 3d ----, 2024 WL 965299, at *36 (N.D. Tex. Mar. 5, 2024).

[32] *SFFA*, 600 U.S. at 212.

[33] 89 Fed. Reg. at 43534.

[34] *Id.* (citing studies showing decreases nationally in racial disparities in rates of deceased donor kidney transplants following introduction of KAS). *See also* Taylor A. Melanson et al., *New Kidney Allocation System Associated with Increased Rates of Transplants Among Black and Hispanic Patients, Health Affairs*, Health Affairs (Millwood): 36(6) at 1078–85 (Jun. 1, 2017), available at https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.1625.

[35] *SFFA*, 600 U.S. at 212.

[36] 89 Fed. Reg. at 43534.

[37] *Id.*

explained, the proposed rule nevertheless remains purposed in, and focused on, achieving, *at least* in part, race-based equity.[38] Indeed, despite the agency's acknowledgments regarding adequate factor control, the agency maintains that racial disparities persist, citing a number of studies throughout the proposed rule that either fail to employ adequate factor control, or outright acknowledge that there are likely "variables that we did not measure and adjust for accounting for the persistent disparity."[39] Consequently, the agency's statements are conflicting and further suggest that any presence or claim of actual racial disparities is tenuous *at best*. Although the government is forbidden from remediating broad racial disparities in any event, these contradictions make any regard for racial equity or generalized racial disparities further unwarranted and nonsensical.[40]

"The entire point of the Equal Protection Clause is that treating someone differently because of their skin color is *not* like treating them differently because they are from a city or from a suburb."[41] In targeting broad societal disparities in kidney transplantation, the agency may very well be "robbing Peter to pay Paul." The government *can* sometimes do that; however, the government may *not* impose its value judgments on the basis of race or for any racially motivated purpose. Such a government-sponsored pitting of racial groups against each other is not only constitutionally forbidden, but also profoundly unethical and immoral, given its application in patient care.

It *should* go without saying that *every* patient who faces kidney failure or ESRD is in desperate need of a kidney transplant. A patient's level of need does not change according to their race, color, ethnicity, or national origin; and one's race does not make them more or less worthy of an organ transplant. All patients deserve—and are entitled to—*equal* treatment, regardless of the color of their skin.

For all the reasons stated herein, WILL opposes CMS's proposed rule and any further implementations thereof. While incentivizing hospitals to boost performance for transplantation access and services would be laudable, the proposed rule is steeped, *at least* in part, in a racially discriminatory purpose and goal; and it is, accordingly, difficult

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[38] As discussed above, both the proposed rule and HHS Secretary Becerra explain how the IOTA Model advances racial equity in "alignment" with the federal government's initiatives and priorities.

[39] *See, e.g.*, 89 Fed. Reg. at 43579 (citing Yue-Harn Ng et al., *Does Racial Disparity in Kidney Transplant Waitlisting Persist After Accounting for Social Determinants of Health*, Transplantation: 104(7) at 1445–55 (July 2020), available at: https://journals.lww.com/transplantjournal/fulltext/2020/07000/does_racial_disparity_in_kidney_transplant.25.aspx. Among many other factors, inadequate factor control includes limitations regarding clinician-reported variables (such as co-morbidities), individual preferences and willing to pursue transplantation, and individual income. *See, e.g., id.* at 43535 (citing Tanjala S. Purnell et al., *Association of Race and Ethnicity With Live Donor Kidney Transplantation in the United States From 1995 to 2014*, JAMA: 319(1) at 49–61 (2018), available at https://jamanetwork.com/journals/jama/fullarticle/2667722).

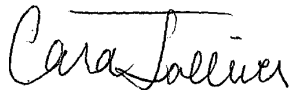
[40] An agency action qualifies as "arbitrary" or "capricious" if it is not "reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021).

[41] *SFFA*, 600 U.S. at 220 (emphasis in original).

to separate out any remaining legitimacy at all. Given the race-based motivations for the rule's creation, as well as the expectations and opportunities for racial discrimination that the HEP requirement would transfer to third parties, CMS "cannot simply ignore" the significant constitutional and legal issues that have presented under this scheme.[42] We urge CMS to address, and take heed of, these significant issues and withdraw the proposed rule.[43]

Sincerely,

WISCONSIN INSTITUTE FOR LAW & LIBERTY, INC.



Cara Tolliver
Associate Counsel

Nathalie E. Burmeister
Associate Counsel

Richard Esenberg
President & General Counsel

Daniel P. Lennington
Deputy Counsel

[42] *See Ohio v. Env't Prot. Agency*, 603 U.S. ----, 2024 WL 3187768, at *7–8 (Jun 27, 2024).

[43] *See Roberts*, 600 U.S. ---- ("in the event that any government again resorts to racial or ethnic classifications to ration medical treatment, there would be a very strong case for prompt review by this Court.").