



July 16, 2024

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

Dear Administrator Brooks-LaSure:

The Global Liver Institute (GLI) and National Alliance for Caregiving (NAC) are pleased to share comments with the Centers for Medicare and Medicaid Services (CMS) on the proposed Increasing Organ Transplant Access (IOTA) Model. This model tests whether performance-based incentives for participating kidney transplant hospitals can increase access to kidney transplants for patients with End Stage Renal Disease (ESRD), while preserving or enhancing quality of care and reducing Medicare expenditures. Performance is measured across three domains: achievement, efficiency, and quality.

We appreciate the proposed model's focus on gaps in the performance of kidney transplant hospitals, including the need to better address health equity as part of to the model's efforts to improve the potential for successful transplantation. CMS states that the best treatment for most patients with kidney failure is kidney transplantation, a valid statement for patients left with no other options. However, prevention is equally important to avoid this extreme outcome. We strongly support the aims of the IOTA model and agree with the importance of a dynamic performance-based risk payment and an equity payment to fundamentally change transplantation incentives to better align with high-quality, equitable care. Our comments call for the IOTA Model to explicitly acknowledge and support the caregivers who play an essential role in achieving the aims of the IOTA Model.

The IOTA Model should explicitly address caregivers.

Caregivers, often-unpaid individuals providing care to family, friends, and those in need with illness and disability, are critical to transplant care. In fact, the transplant system relies heavily on caregivers with transplant recipients typically required to identify an available caregiver who will provide support during and after transplant. It is well recognized that caregivers tend to experience negative consequences to their health and well-being while grappling with a family

member's illness and simultaneously adopting caregiver responsibilities.¹ Transplant caregivers frequently report numerous unmet needs of their own and a lack of resources necessary to meet the demands of their role.

This not only affects caregivers' day-to-day functioning but can also impair their ability to carry out caregiving responsibilities, possibly jeopardizing the success of the transplant patient. Due to the intensity of the transplant experience, family caregivers of the estimated 60,000 transplant patients in the United States face significant consequences to their health, emotional, and financial well-being.

A 2023 report published by NAC titled "Transplant Caregiving in the U.S.: A Call for System Change," that included a review of existing research and interviews with transplant caregivers, health care professionals, and subject matter experts found that transplant caregivers face many challenges, including:

- Significant time and effort commitment: Transplant caregiving can be very demanding, both physically and emotionally. Caregivers often provide around-the-clock care and may have to juggle caregiving with other responsibilities, such as work and family.
- High levels of stress and anxiety: Transplant caregiving can be a very stressful experience, as caregivers worry about the health and well-being of their care recipients. Caregivers may also experience anxiety about the transplant process itself and the potential for complications.
- Lack of support: Many transplant caregivers report that they do not have enough support from others, including family members, friends, and health care professionals. This can lead to feelings of isolation and overwhelm.²

One caregiver stated as part of the NAC report that, "it was a nightmare and I was shocked that I wasn't better prepared via the hospital. And when you leave, it's like the door gets shut. They're so busy with the patients they have that there's no one. There's really no one."

Based on our shared knowledge and experience, GLI and NAC are proud to collaborate in providing recommendations to CMS and (Centers for Medicare and Medicaid Innovation) CMMI that we believe will improve the model by addressing the need for additional caregiver support. While we appreciate the nod to improving caregivers as key participants in the model, our recommendations address the broader—often systemic— gaps that contribute to caregiver strain and hardship so that caregivers are better supported, prepared and equipped to care for transplant patients, thereby playing a role in improving the measured performance of transplant systems in the IOTA Model. Commitment to adequately supporting caregivers of transplant patients through the proposed IOTA Model will undoubtedly have broad implications beyond transplantation for kidneys, including liver transplants, and we urge CMS to prioritize this critical population.

¹ National Alliance for Caregiving & AARP. (2020, May). Caregiving in the U.S. 2020. Retrieved November 1, 2023 from https://www.caregiving.org/wp-content/uploads/2020/06/AARP1316_RPT_CaregivingintheUS_WEB.pdf.

² National Alliance for Caregiving. Transplant Caregiving in the U.S.: A Call for System Change. Retrieved July 1, 2024 from: https://www.caregiving.org/wp-content/uploads/2023/11/NAC_TransplantCaregiversReport-FINAL.pdf

For example, a recent article from the Washington Post discussed the challenges of liver transplantation in Native American communities. We know that inequity begins long before a transplant becomes necessary. Native American patients without access to regular primary care may not be screened for liver disease, which is often treated by gastroenterologists or hepatologists who make referrals to transplant centers when the illness becomes life-threatening. GLI sees many patients drop off at the specialist stage.³ For Native American caregivers facing limited resources, the transplant journey is even more challenging. Access to reliable transportation to faraway appointments, paid time off, and culturally sensitive guidance are often scarce. NAC pointed out that combating the liver disease crisis requires a comprehensive approach that invests in both patients and their caregivers.⁴ By supporting caregivers, these realities can and should be addressed as part of IOTA model to provide lessons for the organ transplantation system more broadly.

Recommendations for Investment of IOTA Model Participants to Improve Quality

Caregiver-Specific Data Collection, Sharing, & Coordination Among Transplant Centers

The stated purpose of the model is to “empower patients, families, and caregivers to actively engage in the transplant journey.” However, the model does not specify how it will integrate and engage caregivers in the transplant journey beyond “interviews” with them. Two key recommendations of the NAC report to accomplish this include: 1) a standardized process for placing individuals in a transplant waitlist that identifies caregivers, and 2) caregiver-specific data collection, sharing, and coordination among transplant centers. Caregiver identification is a critical first step toward documenting, understanding, and addressing the challenges of transplant caregivers. Collecting and sharing caregiver data across centers will provide the information necessary in the creation, refinement, and evaluation of caregiver support best practices.

As a Measure of Performance, Provide Routine Family Caregiver Screenings and Delivery of Support Services to Respond to Unmet Needs at Critical Points Along the Transplant Journey

Caregivers are not consistently nor comprehensively assessed or linked to support resources. There is a need for transplant centers and health care teams to assess and deliver support services that provide resources to reduce caregiver distress and bolster positive patient outcomes. Providing caregiver support can help address health-related social needs and other barriers to care to improve care coordination in the transplant process.

³ <https://www.washingtonpost.com/business/2024/02/08/death-sentence-native-americans-have-least-access-liver-transplant-system/>

⁴ <https://www.washingtonpost.com/opinions/2024/03/08/native-americans-liver-transplants-caregivers/>

The IOTA Model should also promote adoption of a standardized screening process as a necessary first step to address the health-related social needs of both transplant recipients and their caregivers. Unfortunately, we also cannot assume every potential transplant recipient will have a family caregiver. Instead of simply denying transplants to those who do not have a readily identifiable caregiver, we would urge transplant centers to assess the support system for every patient and to identify strategies to augment it. This could involve better supporting family members to be caregivers or implementing strategies to identify caregiving support outside the family unit, such as church members, friends, and community service organizations.

Promote Equitable Access by Dedicating a Coordinator on the Transplant Team to the Family Caregiver.

As part of the IOTA Model, CMS should extend existing Caregiver Training Services (CTS) reimbursement pathways to incentivize health care providers (including nurses and social workers) to train family caregivers in providing the complex medical tasks associated with transplant care. A family caregiver coordinator would serve as the point person for communicating with caregivers throughout the pre- and post-transplant process. This would improve care coordination while supporting the caregiver's health and well-being.

Interviews with Caregivers, Include Questions About Financial Assistance, Workplace Protection, and Medical Coverage Services and Policies for Transplant Caregivers

We encourage the IOTA Model to capture input from caregivers on the impact of federal policies, such as the Family Medical Leave Act (FMLA), that may have implications for the unique care needs in end-stage organ disease and transplantation. Understanding the gaps in federal policy to support caregivers will help policymakers advance new laws and regulations that allow transplant caregivers and patients to balance care and work responsibilities. For example, implementing financial assistance for transplant caregivers and ensuring adequate health coverage would allow them to care for the transplant recipient without jeopardizing their current or future financial situation.

About Global Liver Institute and its efforts to support organ transplantation reforms.

GLI is the leading global liver patient advocacy organization with the mission of improving the lives of individuals and families impacted by liver disease. We promote innovation, encourage collaboration between policymakers, patients, and their clinicians, and work to scale up optimal approaches to help eradicate liver disease. Having been at the forefront of efforts to reform the Organ Procurement and Transplantation Network (OPTN), GLI is pleased that CMMI has invited comments on a proposed model aimed at bringing more accountability to the transplant system, improving health equity for transplant patients and families, and providing a model for improvement beyond kidney transplantation that will benefit the transplant process for livers and other organs. Despite high need and long waiting lists, many viable organs go to waste far too often and too many transplants are not successful due to post-operative challenges that

could be averted with stronger support for caregivers. All signals point to a system in desperate need of improvement.

GLI called for bipartisan reform of the broken transplant system in 2020,⁵ testifying in 2021 at a hearing of the U.S. House Committee on Oversight and Reform, Subcommittee on Economic and Consumer Policy in its bipartisan pursuit of accountability and better performance from the organizations responsible for procuring life-saving organs for transplant.⁶ GLI testified at the Senate Finance Committee hearing about the circuitous route to be diagnosed in liver failure, and evaluated for a transplant, as well as the apparent gaps, inequities, and burdens on families posed by what is called our transplant “system.”⁷ GLI also joined other advocacy organizations in asking CMS to make an initial step in remedying the issue by substituting the metrics by which Organ Procurement Organizations (OPO) are evaluated for a new verifiable metric that is not open to self-reported interpretation⁸ and similarly supported a letter from Senators and Representatives calling on regulators to take measures to oversee and improve OPO performance in the interim given the lives at stake and equity implications.⁹

In response to this collective advocacy, the Health Resources and Services Administration (HRSA) announced the Organ Procurement and Transplantation Network Modernization Initiative.¹⁰ Congress also passed the Securing the U.S. Organ Procurement and Transplantation Network Act, further authorizing much-needed changes to the underlying law to break up the monopoly that the United Network for Organ Sharing (UNOS) holds over the OPTN to allow for innovation and competition while also enhancing accountability and transparency in the national system.¹¹ GLI was honored to join the President at the bill’s Signing Ceremony at the White House and continues to urge its implementation.

About National Alliance for Caregiving and its research on transplant caregivers.

Established in 1996, the NAC is a national membership coalition that brings together more than 50 national health care companies and nonprofits, care innovators, caregiving advocacy

⁵ Donna Cryer, “Bipartisan reform of organ procurement organizations (OPOs) will save lives,” August 24, 2020, <https://globalliver.org/2020-8-bipartisan-reform-of-organ-procurement-organizations-opos-will-save-lives/>.

⁶ Global Liver Institute, “Global Liver Institute CEO Praises U.S. House Subcommittee, Organ Procurement Organization Action to Help Transplant Patients,” May 4, 2021, <https://globalliver.org/2021-05-global-liver-institute-ceo-praises-us-house-subcommittee-organ-procurement-organization-action-to-help-transplant-patients/>.

⁷ Donna Cryer, “Witness Testimony: Liver Transplant Recipient,” July 20, 2023, https://www.finance.senate.gov/imo/media/doc/0720_cryer_testimony.pdf.

⁸ Global Liver Institute, “Global Liver Institute Sends Request to CMS for OPO Metric Fix,” March 12, 2019, <https://www.ajmc.com/view/global-liver-institute-sends-request-to-cms-for-opo-metric-fix>.

⁹ Cory Booker Press Office, “Booker, Jones Lead Colleagues in Urging HHS, CMS, and HRSA to Improve OPO Performance and Increase Access to Organ Transplantations,” November 29, 2022, <https://www.booker.senate.gov/news/press/booker-jones-lead-colleagues-in-urging-hhs-cms-and-hrsa-to-improve-opo-performance-and-increase-access-to-organ-transplantations>.

¹⁰ HRSA Press Office, “HRSA Announces Organ Procurement and Transplantation Network Modernization Initiative,” March 22, 2023, <https://www.hrsa.gov/about/news/press-releases/organ-procurement-transplantation-network-modernization-initiative>.

¹¹ Global Liver Institute, “Global Liver Institute Thanks President Biden for Signing the Securing the U.S. Organ Procurement and Transplantation Network Act into Law,” September 27, 2023, <https://globalliver.org/global-liver-institute-thanks-president-biden-for-signing-the-securing-the-u-s-organ-procurement-and-transplantation-network-act-into-law/>.

organizations, and financial services leaders to advance a common agenda of building health, wealth, and equity for America's 53 million family caregivers. From championing the nation's first-ever national caregiving strategy to releasing new insights on the realities of caregiving, NAC works tirelessly to make caregiving more sustainable and equitable through agenda-setting research, programming, and policy change.

NAC's research on transplant caregiving highlights the vital role and limited attention paid to the experiences and needs of transplant caregivers.² They provide essential physical and emotional support before, during, and after surgery, and their contributions are critical to the success of the transplant process.

Conclusion

We appreciate that the IOTA Model seeks to address many of the most pressing barriers to kidney transplantation in hopes of advancing best practices across providers. In our experience, patients and caregivers have identified the most significant challenges as getting information, the waitlist process, post-transplant support, and access to and quality of care throughout the entire process. It is our hope that as you advance this new care model, support for caregivers is a central component of measuring the performance of providers.

Thank you for your consideration.

Sincerely,



Donna R. Cryer, JD
President & CEO
Global Liver Institute



Jason Resendez,
President & CEO
National Alliance for Caregiving