

June 8, 2026

John C. Magee, MD President, OPTN Board of Directors Jeremiah & Claire Turcotte Professor of Transplant Surgery University of Michigan Medical Center

And All Members of the OPTN Board of Directors

Via Official Public Comment Channel: optn@unos.org

RE: Formal Submission — A Lean Six Sigma Methodology for Transformation of the United States Solid Organ Transplant System, Version 2.0 (June 2026), Cold Ischemia Foundation

Dear President Magee and Members of the OPTN Board of Directors:

I. STANDING AND PURPOSE OF THIS SUBMISSION

The Cold Ischemia Foundation (CIF) is a grassroots structural healthcare advocacy organization based in Ellenton, Florida, Congressional District FL-16. CIF was founded by Jeff A. Parke — a three-time kidney transplant recipient — and Marie Parke, RN, a radiation oncology nurse with fourteen years of clinical experience who has served as care partner through all three transplant episodes spanning seventeen years. CIF operates under a founding constitutional constraint of zero pharmaceutical, dialysis, or insurance industry funding. This constraint is not a marketing statement. It is a governance structure, established because the advocacy space for transplant reform is substantially captured by industry funding relationships whose conflicts of interest are directly relevant to the failures this submission documents.

This letter formally transmits CIF's white paper —

A Lean Six Sigma Methodology for Transformation of the United States Solid Organ Transplant System, Version 2.0, June 2026 — to the OPTN Board of Directors for review, consideration, and engagement.

This submission is made pursuant to the Board's stated commitment to transparency, public engagement, and evidence-based policy development. It is submitted in good faith, with the expectation that factual errors, if any exist, will be identified and corrected. The Cold Ischemia Foundation has no financial interest in any specific policy outcome. Our interest is in a transplant system that works for the 90,000 people on the waiting list, the 13 who die each day, the living donors who are turned away by addressable barriers, and the care partners whose labor the system requires but does not recognize.

II. SUMMARY OF THE DOCUMENT

The white paper applies Lean Six Sigma's DMAIC framework — Define, Measure, Analyze, Improve, Control — to the U.S. solid organ transplant system at the national policy level. It is 55 pages, contains ten data visualizations including two novel LSS strategic tools, cites 54 peer-reviewed and primary sources verified against PubMed, the Cochrane Library, JAMA Internal Medicine, the American Journal of Transplantation, CMS rulemaking documents, and HRSA directives. It is the first application of full DMAIC methodology to the U.S. transplant system at the policy level in the published literature.

Five findings warrant the Board's specific attention:

- **The kidney non-use rate breached the upper control limit on a statistical process control chart in 2023, satisfying Nelson Rule 1 criteria for a process no longer in statistical control.** The mean shift began with KAS250 implementation in March 2021. The root cause is a structural misalignment between federal allocation policy and CMS quality metrics — a Nash equilibrium in which individual transplant centers behave rationally while the aggregate system discards thousands of transplantable kidneys annually. The IOTA Model partially addresses this for approximately 41 percent of hospitals. The remaining 59 percent continue to operate under the old incentive structure.
- **92.8 percent of potential living donors are lost before completing donation.** The barrier-stack model documents compound attrition across six filter stages. The financial filter is the largest single policy-addressable barrier: the NLDAC reimburses an average of \$2,350 per donor against documented costs exceeding \$5,500, while the National Kidney Registry's Donor Shield program demonstrates that \$24,000 in coverage is achievable. The Living Donor Protection Act — first introduced in 2016 — has not been enacted. These are not unsolvable problems. They are unfunded solutions.
- **The IOTA Model expires June 30, 2031.** Without codification into permanent Conditions of Participation before that date, six years of institutional adaptation reverts overnight. CIF's position is that IOTA provides the correct incentive architecture — explicitly rewarding transplant volume and organ utilization — but insufficient coverage and zero permanence in its current form. The Board should actively advocate for IOTA's codification as the single most consequential near-term policy action available.
- **Care partners to kidney transplant recipients contribute an estimated \$1.37 billion in uncompensated labor annually.** Transplant Conditions of Participation effectively mandate care partner participation as a condition of access to transplantation, yet no federal program recognizes, compensates, or protects this labor. Marie Parke, RN — CIF's co-founder — has a documented care partner labor invoice of \$466,000 over seventeen years. At national scale, this is a \$1.37 billion annual blind spot in the system's cost accounting. The Marie's Lifeline Compensation Act provides a CMS 1115 waiver implementation pathway.
- **The transplant system's equity failures are performance failures, not distributional concerns.** Non-Hispanic Black patients aged 18 to 29 are 27 percent less likely to be waitlisted than non-Hispanic White patients (Husain et al., JAMA Internal Medicine, 2023). The Black living donor share declined 36 percent between 2011 and 2022 — a decade of overall living donor growth — without any mandatory corrective mechanism triggering. These are out-of-control signals in a system that claims to allocate organs based on medical need.

III. SPECIFIC REQUESTS OF THE BOARD

CIF makes three specific requests of the OPTN Board of Directors:

- **Adopt quarterly SPC governance for the eight core metrics identified in Section 6.1.** The non-use rate has been in statistical non-control since 2021. A process that cannot detect its own out-of-control signals cannot correct them. Mandatory root cause review within 60 days of any Nelson Rule violation — with results published publicly — is operationally achievable within current OPTN authority.
 - **Formally advocate to CMS for IOTA permanence before 2029.** The independent OPTN Board has standing to submit formal comment to CMS. A Board resolution supporting the codification of IOTA performance domain weights into permanent Conditions of Participation — submitted before the December 2026 proposed rule comment deadline — would carry structural weight that no patient advocacy organization can replicate. This Board exists precisely for this moment.
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IV. A NOTE ON INDEPENDENCE

The Cold Ischemia Foundation is aware that this submission is confrontational in places. It names specific structural failures, attributes them to specific policy decisions, and identifies specific stakeholder groups whose financial interests are served by the status quo. We do not apologize for that. The transplant system has had comprehensive, polite, well-documented reform proposals for decades. Thirteen people die every day waiting for a kidney transplant. Politeness has not moved the needle.

CIF's founding constraint of zero pharmaceutical, dialysis, or insurance industry funding means we have no financial relationship to protect in making these arguments. Fresenius Medical Care and DaVita together control approximately 70 percent of the U.S. dialysis market and have extensive funding relationships with patient advocacy organizations that nominally support transplant access. Each successful kidney transplant eliminates approximately \$145,000 in annual dialysis revenue. That financial stake in transplant underperformance is not incidental to the reform environment. It is constitutive of it. The Board should be aware of which organizations making representations to it have financial relationships with dialysis industry funders — and which do not.

The Cold Ischemia Foundation does not.

The white paper is attached to this submission and available at coldischemia.foundation. CIF welcomes direct engagement, factual challenge, and collaboration with any Board member, committee, or staff who wishes to engage with the analysis.

The infrastructure for transformation exists. The evidence base is comprehensive. The legislative vehicles are introduced. What the system has historically lacked is the accountability pressure that converts known, evidence-based reforms into implemented, enforced, and permanent policy change. That is what this organization exists to supply — and what this Board, uniquely in the forty-year history of OPTN governance, now has the structural independence to demand.

Respectfully submitted,

Jeff A. Parke

Founder Cold Ischemia Foundation

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Enclosure: A Lean Six Sigma Methodology for Transformation of the United States Solid Organ Transplant System — Version 2.0, June 2026.

cc: HRSA Administrator Tom Engels | HRSA OPTN Modernization Team | CMS IOTA Model Team | Senate HELP Committee | House Energy and Commerce Committee

The Cold Ischemia Foundation accepts zero pharmaceutical, dialysis, or insurance industry funding — by constitutional constraint, not preference.

OPTN Board of Directors

Current Membership as of June 2026 | Source: HRSA / optn.transplant.hrsa.gov

#	Name	Board Role / Seat Type	Affiliation
1	John C. Magee, MD	President	University of Michigan
2	Shelley Hall, MD	Vice President	Baylor University Medical Center
3	William (Bill) Ryan, MBA	Vice President, Patient/Donor Affairs	Transplant Life Foundation
4	Alan Reed, MD, MBA, FACS	Treasurer	University of Iowa Health Care
5	Justin Wilkerson, MBA	Secretary	Illinois Army National Guard
6	Dan Meyer, MD	Transplant Physician/Surgeon	Baylor Scott & White Health – Dallas
7	Kymberly D. Watt, MD	Transplant Physician/Surgeon	Mayo Clinic
8	George Bayliss, MD	Transplant Physician/Surgeon	Rhode Island Hospital / Brown University
9	Joseph Magliocca, MD	Transplant Physician/Surgeon	Vanderbilt University Medical Center
10	John J. Sperzel III, BS	Patient/Donor/Family Representative	Former Chairman & CEO, T2 Biosystems
11	Gitthaline (Candie) Gagne, USN, HM1 (Ret.)	Patient/Donor/Family Representative	Retired U.S. Navy / UPMC McKeesport
12	Peter Nicastro, MS, MBA (Deceased)	Patient/Donor/Family Representative	Previously Cigna
13	Jen Benson, BA	Patient/Donor/Family Representative	The Transplant Journey Inc.

#	Name	Board Role / Seat Type	Affiliation
14	James Cason, MA	Patient/Donor/Family Representative	Former Mayor, Coral Gables, FL
15	Cody Reynolds	Patient/Donor/Family Representative	Parent of Pediatric Transplant Recipient
16	John Hodges, MA	Patient/Donor/Family Representative	Formerly Boston University
17	Samantha Endicott, MPH, CPTC	OPO Representative	New England Donor Services
18	Darren Lahrman, MBA, CPTC, BSRC	OPO Representative	LifeLink of Florida
19	Kevin Lee, MPA	OPO Representative (At Large)	Mid-America Transplant
20	Joshua Gossett, DNP, MBA, RN, FACHE	Transplant Hospital Representative	Lucile Packard Children's Hospital Stanford
21	Annette Needham, DNP, NP-C, NEA-BC, CCTC	Voluntary Health Assoc. Representative	UC Davis Transplant Center / NATCO
22	Cathi Murphey, PhD, MS	Histocompatibility Representative	Southwest Immunodiagnostics, Inc.
23	Jerold Mande, MPH	Non-Transplant Professional	Nourish Science / Harvard Chan School
24	Mary E. Homan, DrPH, MA, MSHCE	Non-Transplant Professional	CommonSpirit Health
25	Nahel Elias, MD	Regional Councillor – Region 1	Massachusetts General Hospital
26	Kenneth Chavin, MD, MBA, PhD	Regional Councillor – Region 2	Temple University Health System
27	Ari Cohen, MD, MBA	Regional Councillor – Region 3	Ochsner Health System
28	Ryan Davies, MD	Regional Councillor – Region 4	UT Southwestern / Children's Medical Center
29	Andrew M. Courtwright, MD, PhD	Regional Councillor – Region 5	University of Utah
30	Gina-Marie Barletta, MD	Regional Councillor – Region 6	Oregon Health & Science University
31	Reynold Lopez-Soler, MD, PhD	Regional Councillor – Region 7	Loyola University Medical Center
32	Mark Wakefield, MD	Regional Councillor – Region 8	University of Missouri Health Care
33	Meelie DebRoy, MD	Regional Councillor – Region 9	Westchester Medical Center
34	Austin Schenk, MD, PhD, FACS	Regional Councillor – Region 10*	Ohio State University
35	Vincent Casingal, MD	Regional Councillor – Region 11	Atrium Health / Carolinas Medical Center
36	Steven Weitzen, J.D.	Director (Appointed April 2026)	Filling vacancy – term ends June 30, 2029