



November 13, 2023

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The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Discrimination on the Basis of Disability in Health and Human Service Programs or Activities.

Dear Secretary Becerra,

Global Liver Institute (GLI) welcomes the opportunity to provide comments on the proposed rulemaking for implementation of Section 504 of the Rehabilitation Act. GLI is the leading global liver patient advocacy organization with a mission to improve the lives of individuals and families impacted by liver disease through promoting innovation, encouraging collaboration, and scaling optimal approaches to help eradicate liver disease. We are signatories on a separate letter addressing the proposed rule's provisions on Medical Treatment and Value Assessment. Therefore, our comments here will focus on organ transplantation.

As background, GLI has been at the forefront of efforts to reform the Organ Procurement and Transplantation Network (OPTN). In 2022, a total of 42,800 organs were transplanted in the U.S., yet thousands of people still die each year while on the transplant waiting list.¹ According to the Health Resources and Services Administration (HRSA) a new person is added to the transplant

¹ UNOS News Bureau, "2022 organ transplants again set annual records; organ donation from deceased donors continues 12-year record-setting trend," January 10, 2023, <https://optn.transplant.hrsa.gov/news/2022-organ-transplants-again-set-annual-records-organ-donation-from-deceased-donors-continues-12-year-record-setting-trend/#:~:text=In%20brief%3A,liver%2C%20heart%20and%20lung%20transplants.>

waiting list every 10 minutes.² Despite high need and long waiting lists, many viable organs go to waste far too often. All signals point to a system in desperate need of improvement.

As GLI's founder and CEO, on behalf of liver disease and liver cancer patients, I called for bipartisan reform of the broken transplant system in 2020,³ 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.⁴ More recently, I was a witness at the Senate Finance Committee hearing where I discussed how I navigated 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."⁵

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 interpretation⁶ 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.⁷

In response to this collective advocacy, HRSA announced the Organ Procurement and Transplantation Network Modernization Initiative, which aims to update the existing donation database, contract more organizations to share the burden of the responsibilities that are currently managed solely by UNOS and increase investment in organ procurement and transplantation.⁸ Congress also passed the Securing the U.S. Organ Procurement and Transplantation Network Act to further authorize much-needed changes to the underlying law that will break up the monopoly that the United Network

² HRSA, "Organ Donation Statistics," March 2023, <https://www.organdonor.gov/learn/organ-donation-statistics>.

³ 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/>.

⁴ 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/>.

⁵ Donna Cryer, "Witness Testimony: Liver Transplant Recipient," July 20, 2023, https://www.finance.senate.gov/imo/media/doc/0720_cryer_testimony.pdf.

⁶ 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>.

⁷ 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>.

⁸ 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>.

for Organ Sharing (UNOS) holds over the OPTN to allow for innovation and competition while also enhancing accountability and transparency in the national system.⁹ I was honored to join the President at the bill's Signing Ceremony at the White House.

With this background, on behalf of liver transplant patients, we agree that the organ transplant system requires much-needed enforcement against discrimination, including against people with disabilities. We were pleased to see that the Office for Civil Rights has investigated these acts of discrimination, finding that patients with disabilities who are otherwise qualified for transplant eligibility are too often not placed on transplant waiting lists, despite being qualified, because of exclusions and limitations for certain disabilities that are not supported by objective evidence or that do not take into account reasonable modifications in assessing an individual's ability to manage postoperative care needs and other aspects of transplantation. The persistence of this discrimination can only be addressed with clear guidance and enforcement against it. GLI applauds this effort to advance a rule that specifically discusses the application of section 504's requirements in the medical treatment context.

It is important to also note the importance of this proposed rule for advancing health equity more broadly. For people of color, the unrealized potential of organ transplantation is even more devastating. We know people of color are significantly *less* likely to be put on the waitlist, and also less likely than white patients to receive a life-saving organ transplant once on the waitlist.¹⁰ While white people on the waitlist have about a 50% chance of getting a transplant each year, the number is closer to 25% for Black people.¹¹ Studies also reveal the strong bias against Black people when it comes to assessing the "fit" of getting a transplant. In reality, people of color are more likely to be deemed medically unfit based on a nonclinical assessment highly subject to racial bias, or they may not be informed of the option at all.¹² For example, historically Black patients were less likely to be referred by hospital staff to OPOs,¹³ including as the result of guidance by OPOs to not call them in specific circumstances "to avoid reporting on cases when the OPO believes donation is unlikely."¹⁴ African Americans are more likely than Non-Hispanic Whites to have a disability in every age

⁹ 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/>.

¹⁰ Bloom Works, "Inequity in Organ Donation," <https://bloomworks.digital/organdonationreform/Inequity/#fn:23>.

¹¹ OMH, "Organ Donation and African Americans," October 31, 2022, <https://minorityhealth.hhs.gov/organ-donation-and-african-americans>.

¹² Bloom Works, "Inequity in Organ Donation," <https://bloomworks.digital/organdonationreform/Inequity/>.

¹³ Laura A. Siminoff, Renee H. Lawrence, Robert M. Arnold, "Comparison of black and white families' experiences and perceptions regarding organ donation requests," January 31, 2003, <https://pubmed.ncbi.nlm.nih.gov/12545008/>.

¹⁴ Bloom Works, "Inequity in Organ Donation," <https://bloomworks.digital/organdonationreform/Inequity>.

group, creating a compounding effect of discrimination against people who are Black, disabled and in need of an organ transplant.¹⁵

We would also strongly urge the final rule to acknowledge the discrimination experienced by organ donors with disabilities who are assumed to be “unfit” to donate an organ based on their disability. The same stereotypes and biases that are experienced by people with disabilities seeking an organ transplant may be experienced by people seeking to be an organ donor. Currently, the OPTN regulations state, “Living donor recovery hospitals may exclude a donor with any condition that, in the hospital’s medical judgment, causes the donor to be unsuitable for organ donation.”¹⁶ Such broad language opens the door for medical professionals to impose their bias on individuals with disabilities whose organs may be suitable for transplant but whose disability is viewed as inherently making them unfit to be a donor. By acknowledging that the Medical Treatment section of the final rule applies to both recipients and donors, living donor recovery hospitals will be on notice that this type of bias violates Section 504.

Also, the Living Donor Protection Act, legislation currently introduced in Congress, is intended to eliminate the barriers to organ donation that stem from insurance companies denying or limiting coverage and from charging higher premiums for living organ donors and policies excluding living organ donation from being considered a serious health condition triggering Family and Medical Leave. As with being the recipient of an organ transplant, accommodations may be needed to ensure people with disabilities are able to be living donors. The need for such accommodations should not trigger assumptions that a person with a disability is not fit to donate. Additionally, people with disabilities should not be subjected to bias and stereotypes that preclude them from being organ donors in life or in death simply based on assumptions about the fitness of their organs for donation that are not supported by medical evidence.

In closing, we appreciate the agency’s efforts to advance this proposed rule and to make it clear that the section on Medical Treatment applies to discrimination experienced by people with disabilities in need of an organ transplant. We hope the agency will also consider also explicitly recognizing the rule’s application to people seeking to be organ donors.

¹⁵ Kelvin Boston, Nanette Goodman, Michael Morris, “Financial Inequality: Disability, Race and Poverty in America,” September 13, 2017, <https://www.nationaldisabilityinstitute.org/wp-content/uploads/2019/02/disability-race-poverty-in-america.pdf>.

¹⁶ Living Donor Exclusion Criteria, OPTN Policies, Section 14.4.E, https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf

Sincerely,

A handwritten signature in black ink that reads "Donna R. Cryer". The signature is written in a cursive, flowing style.

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

About Global Liver Institute

Global Liver Institute (GLI) was built to solve the problems that matter to liver patients, equipping advocates to improve the lives of individuals and families impacted by liver disease. GLI promotes innovation, encourages collaboration, and supports the scaling of optimal approaches to help eradicate liver diseases. GLI believes liver health must take its place on the global public health agenda commensurate with the prevalence and impact of liver illness. GLI is the only patient-created, patient-driven nonprofit organization tackling liver health and all liver disease holistically, operating globally. Follow GLI on [Facebook](#), [Instagram](#), [LinkedIn](#), and [YouTube](#).

