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February 18, 2021

Xavier Becerra
Secretary-Designee
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Neera Tanden
Director Nominee
Office of Management and Budget
725 17th St NW
Washington, DC 20503

Dr. Marcella Nunez-Smith,
Chair of the COVID Equity Task Force
The White House
1650 Pennsylvania Ave NW
Washington DC 20502

RE: Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Final rule

Dear Secretary-Designee Becerra, Director Nominee Tanden, and Dr. Nunez-Smith,

Global Liver Institute (GLI) is a nonpartisan nonprofit patient advocacy organization committed to improving the lives of individuals and families impacted by liver disease by promoting innovation, encouraging collaboration, and scaling optimal approaches to help eradicate liver diseases. We applaud the steps that the Biden-Harris administration has already taken to seek and then follow recommendations from the scientific community during the deadly COVID-19 pandemic. The administration's early actions clearly recognize the value of collaboration and that investments in public health, along with scientific discovery, are crucial to improving the nation's health and economy in both the near- and

long-term.

With this understanding, we write to you today to respectfully request that you urgently advance the U.S. Department of Health and Human Services' (HHS) recently published lifesaving, pro-patient regulations titled "Medicare and Medicaid Programs; Organ Procurement

Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Final rule.”¹

Collectively, liver diseases impact more than 120 million Americans. Over the last year, the burden of liver disease has only intensified due to the impact of COVID-19 on overall liver health as well as our healthcare system.^{2 3} Many people impacted by liver disease are at an increased risk of their disease progressing to more serious stages with life-threatening complications like cirrhosis, liver cancer, and other end-stage liver diseases. In these dangerous situations, a liver transplant is their only hope.

Before the COVID-19 pandemic, on average there would be more than 13,000 liver patients in the U.S. waiting for a lifesaving transplant every year, and, sadly, three people would die everyday while waiting.⁴ Now with the increased risk of organ failure in addition to the serious health outcomes due to COVID-19, those same patients are at an even greater risk of death.^{5 6} On top of these startling numbers is the reality that from getting on the waitlist, to finding a match, to becoming a donor, patients of color who need an organ have more adverse experiences within an organ donation system deeply rooted in inequity.⁷

From viral hepatitis to fatty liver disease and nonalcoholic steatohepatitis, minority populations are disproportionately impacted by liver disease. For example, Asian Americans are four times more likely to have hepatocellular carcinoma,⁸ one of the most common indications for liver transplant. Coupled with this stark reality is the high prevalence of comorbidities such as diabetes, hypertension, obesity, hepatitis B and C, in minority groups, resulting in racial minorities being disproportionately represented on transplant waiting lists.⁹ Adding COVID-19 to the equation has only exacerbated these long-standing racial and ethnic health disparities that we have sought to eliminate for years.

In response to this crisis, we need urgent congressional oversight and administration action! Strategies must address racial obstacles to getting on the waitlist, increasing medically suitable organs available for patients of color, and improving the likelihood of potential donors of color to be referred. Most critically we must address the actions of the network of government contractors - called organ procurement organizations (OPOs) - that run the organ donation system. In some cases, OPOs have not shown up to talk to donor families of color, failed to get proper authorization, nor found a correct donor/organ match.

This is why, in July of 2019, we could not have been more excited to see a positive first step taken by the prior administration to modernize this system. Since July 2019 we have continued advocating for these positive changes through official submitted comments dated September 27, 2019, and multiple letters to agency and congressional leadership. Late last year, at last, we

¹ <https://www.cms.gov/files/document/112020-opo-final-rule-cms-3380-f.pdf>

² [https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370\(20\)30432-6/fulltext](https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(20)30432-6/fulltext)

³ <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/liver-disease.html>

⁴ Organ Procurement Transplantation Network, U.S. Department of Health and Human Services

⁵ [https://www.journal-of-hepatology.eu/article/S0168-8278\(20\)30305-6/fulltext#%20](https://www.journal-of-hepatology.eu/article/S0168-8278(20)30305-6/fulltext#%20)

⁶ https://natap.org/2020/AASLD/AASLD_116.htm

⁷ “[Comparison of black and white families’ experiences and perceptions regarding organ donation requests.](#)” Crit Care Med, 2003

⁸ “[Role of Ethnicity in Risk for Hepatocellular Carcinoma in Patients With Chronic Hepatitis C and Cirrhosis.](#)” CGH Journal, 2004.

⁹ Kemmer N. (2011). Ethnic disparities in liver transplantation. *Gastroenterology & hepatology*, 7(5), 302–307.

witnessed HHS and the Centers for Medicare & Medicaid Services (CMS) finalize these much-needed and long-overdue new regulations.

These rules are projected to save more than 7,300 lives per year.¹⁰ They will install basic transparency and accountability measures for OPOs. Furthermore, they will ensure safe, high-quality care that puts patients first by: supporting higher donation rates; reducing discarded but viable organs; and modernizing organ recovery and transplantation. Most importantly, these measures will incentivize OPOs to invest in serving their entire community, which includes hiring more diverse staff and investing more time and resources to develop relationships with underserved populations and the hospitals that serve them.

GLI is not alone in showing our support of these vital changes. These reforms have received bipartisan congressional support from Senators Ron Wyden, Chuck Grassley, Todd Young, both Co-Chairs of the House Kidney Caucus, both of the House Diabetes Caucus, the Chair of the Congressional Black Caucus, and Representative Katie Porter. We have also been joined by many other leaders in the advocacy community including the National Kidney Foundation, and American Society of Nephrology.

These lifesaving rules will positively shorten waiting lists and save lives by incentivizing OPOs to increase the number of safe, timely transplants. These measures also act as a prompt and strategic approach for the Administration to provide immediate support to communities of color who have always been hit hardest by liver disease.

In conclusion, we commend your actions thus far. You have demonstrated your commitment to the support and treatment of all Americans, especially during a global crisis. However, as patients for whom access to a liver transplant is literally a life-and-death issue, we respectfully urge you to move forward with these organ donation reforms immediately. Any further delays in implementation are a death sentence for many of our most vulnerable patients.

If you have any questions, please don't hesitate to reach out to our Policy Director, Andrew Scott, at ascott@globalliver.org or 831-246-1586.

Sincerely,



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

¹⁰<https://www.hhs.gov/about/news/2020/11/20/hhs-secretary-azar-statement-final-rule-increase-access-lif esaving-organs.html>