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United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

March 16, 2021

VIA ELECTRONIC TRANSMISSION

Norris Cochran
Acting Secretary
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; 85 FR 77898

Dear Acting Secretary Cochran,

We write in strong support of the Centers for Medicare & Medicaid Services final rule revising performance and outcomes measures, increasing accountability, and improving transparency through changes to the Organ Procurement Organization (OPO) Conditions for Coverage (CfCs) and to request that it be expeditiously implemented.¹ Since 2015, an average of more than 12,000 people died each year while waiting for a transplant or were removed from the waiting list due to becoming too sick to undergo transplantation.² Reforming the standards to which OPOs are held is an important step in improving the organ transplant system.

This Final Rule marks a critical first step toward ensuring accountability across all 57 OPOs in the United States. Prior to the regulation, CMS surveyed OPOs as part of a recertification process every four years, in order to assess whether they have met the CfCs including outcome and process measures.³ In the last survey the agency stated that “the current

¹ Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization, 85 Fed. Reg. 77898 (published Dec. 02, 2020) (42 C.F.R. Part 486) (CMS-3380-F) available at, <https://www.federalregister.gov/documents/2020/12/02/2020-26329/medicare-and-medicaid-programs-organ-procurement-organizations-conditions-for-coverage-revisions-to>.

² See “Transforming Organ Donation in America,” THE BRIDGESPAN GROUP (Nov. 2020), available at <https://www.bridgespan.org/bridgespan/Images/articles/transforming-organ-donation-in-america/transforming-organ-donation-in-america-november2020.pdf>.

³ CTRS. FOR MEDICARE AND MEDICAID SERV., “CMS Fact Sheet: Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F,” (Nov. 20, 2020), available at, <https://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos>.

OPO outcome measures are not sufficiently objective and transparent to ensure appropriate accountability in assessing OPO performance.”⁴ The Department’s own data suggests that thousands of lifesaving organs have gone unrecovered every year.⁵ Additionally, Inspector General audits and reports,⁶ whistleblower accounts,⁷ and investigative reporting⁸ have found OPO performance failures, as well as instances of patient safety endangerment.⁹

GAO found that the revisions in the final rule would “increase donation rates and organ transplantation rates by replacing the current outcome measures with new transparent, reliable, and objective outcome measures” and increase competition for control of open organ donation service areas.¹⁰ According to data from the Department of Health and Human Services (HHS), this rule will save more than 7,000 lives every year.¹¹ CMS also estimates that if every OPO were to meet or exceed just the proposed OPO transplantation rate measure, “we could increase the number of annual transplants from approximately 33,000 to 41,000 by 2026.”¹² Furthermore, by increasing kidney transplants and avoiding dialysis costs to Medicare, OPO reform could save taxpayers up to \$40 billion over the next 10 years.¹³

⁴ Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization, 85 Fed. Reg. 77898 (published Dec. 02, 2020) (42 C.F.R. Part 486) available at <https://www.federalregister.gov/documents/2020/12/02/2020-26329/medicare-and-medicare-programs-organ-procurement-organizations-conditions-for-coverage-revisions-to>.

⁵ 85 Fed. Reg. 77898, *supra* note 2.

⁶ U.S. DEP’T OF HEALTH & HUMAN SERV., OFFICE OF INSPECTOR GEN., [Hereinafter “OIG”], A-09-08-00033, “Review of OneLegacy’s Reported Fiscal Year 2006 Organ Acquisition Overhead Costs and Administrative and General Costs” (Jan. 2010), available at <https://oig.hhs.gov/oas/reports/region9/90800033.pdf>. See also, OIG, A-09-09-00087, Review of California Transplant Donor Network’s Reported Fiscal Year 2007 Organ Acquisition Overhead Costs and Administrative and General Costs (Oct. 2010), available at <https://oig.hhs.gov/oas/reports/region9/90900087.pdf>.

⁷ Alex Ferrer, “Whistleblower threatened with being cremated alive after exposing mortuary kickback scheme,” CBS NEWS (June 14, 2019), (reporting that after blowing the whistle to expose how taxpayers were being “ripped off,” the whistleblower was “blackballed” from the entire industry, his boss threatened to “kill his family, and told him that he would be “cremated alive.”), available at <https://www.cbsnews.com/news/whistleblower-threatened-with-being-cremated-alive-after-exposing-mortuary-kickback-scheme/>.

⁸ See “How Lifesaving Organs For Transplant Go Missing In Transit,” KAISER HEALTH NEWS, available at https://khn.org/news/how-lifesaving-organs-for-transplant-go-missing-in-transit/amp/?utm_source=STAT%20Newsletters&utm_campaign=06e49f9ea7-MR_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-06e49f9ea7-149550985&_twitter_impression=true. See also, Adam Zagorin, “Heartless: Organ Donation Contractors Lobby Against a Popular Health Care Initiative While Pocketing Pandemic Relief Loans,” PROJECT ON GOVERNMENT OVERSIGHT (POGO) (Oct. 5, 2020), available at <https://www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/>.

⁹ Mary Katherine Wildeman, “He Died When He Got the Wrong Lungs. It Wasn’t the Only Organ Error in SC that Day.” THE POST AND COURIER (Sept. 11, 2020), available at https://www.postandcourier.com/health/he-died-when-he-got-the-wrong-lungs-it-wasnt-the-only-organ-error-in/article_c6a6e386-e704-11ea-91ce-2783df6c6f2d.html.

¹⁰ GOV’T ACCOUNTABILITY OFFICE, File B-332771 (Dec. 16, 2020), available at <https://www.gao.gov/products/B-332771>.

¹¹ Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization, 85 Fed. Reg. 77898 (published Dec. 02, 2020) (42 C.F.R. Part 486), available at <https://www.federalregister.gov/documents/2020/12/02/2020-26329/medicare-and-medicare-programs-organ-procurement-organizations-conditions-for-coverage-revisions-to>.

¹² CENTERS FOR MEDICARE AND MEDICAID SERV., “CMS Fact Sheet: Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F,” (Nov. 20, 2020), available at <https://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos>.

¹³ See “Transforming Organ Donation in America,” THE BRIDGESPAN GROUP (Nov. 2020), available at <https://www.bridgespan.org/bridgespan/Images/articles/transforming-organ-donation-in-america/transforming-organ-donation-in-america-november2020.pdf>.

These reforms also have urgent implications for health equity, as failures of the current organ donation system disproportionately hurt patients of color.¹⁴ Communities of color are much more likely to need lifesaving organ transplants, yet research shows that as a result of differential OPO performance and treatment of Black families, they are much less likely to receive them than clinically similar white patients.¹⁵ Ben Jealous, former President of the National Association for the Advancement of Colored People wrote in support of the OPO final rule, “Despite near-universal support for organ donation in the United States, people of color, and Black people in particular, are systematically disadvantaged at every step of the system, all for reasons as unacceptable as they are rectifiable... Too often, organ procurement organizations do not prioritize organ recovery from Black patients.”¹⁶ Prioritizing organ recovery from Black patients is imperative, as Black donors are more frequently matches for Black recipients. Experts project a dramatically increased need for transplants as a result of COVID-19,¹⁷ which is likely to compound the disparities already experienced by minority populations.¹⁸

Reforming the U.S. transplant system is a bipartisan issue, with efforts beginning under the Obama Administration and continuing through the Trump Administration. Additionally, this data-informed rule has the support of every major patient group engaged on this issue, all five former (bipartisan) HHS Chief Technology Officers,¹⁹ and advocacy groups ranging from Families USA²⁰ to FreedomWorks,²¹ as well as leading economists,²² industry associations,²³ doctors and researchers,²⁴ and data scientists including DJ Patil, the former Chief Data Scientist of the United States.²⁵ We also note the ongoing investigations from the Senate Finance

¹⁴ See “The Costly Effects of an Outdated Organ Donation System,” BLOOM WORKS (Oct. 2020), (specifying that in terms of potential organ recipients, people of color “are less likely to get on the [national organ transplant] waitlist and less likely to find a match once they’re on there.”) (The Committee is looking into the racial disparities in the organ donation system, as highlighted by this recent report.), available at <https://bloomworks.digital/organdonationreform/Inequity/>.

¹⁵ See “The Costly Effects of an Outdated Organ Donation System,” BLOOM WORKS (Oct. 2020), (specifying that in terms of potential organ recipients, people of color “are less likely to get on the [national organ transplant] waitlist and less likely to find a match once they’re on there.”) (The Committee is looking into the racial disparities in the organ donation system, as highlighted by this recent report.), available at <https://bloomworks.digital/organdonationreform/Inequity/>.

¹⁶ Jealous, Ben, et al. “New Organ Donation Rule Is A Win for Black Patients and Health Equity,” HEALTH AFFAIRS (Dec. 17th 2020), available at <https://www.healthaffairs.org/doi/10.1377/hblog20201211.229975/full/>

¹⁷ Sperati, Christopher. “Coronavirus: Kidney Damage Caused by COVID-19,” JOHNS HOPKINS MEDICINE (Mar 14, 2020), available at, <https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/coronavirus-kidney-damage-caused-by-covid19>.

¹⁸ Centers for Disease and Control. “COVID-19 Racial and Ethnic Health Disparities,” available at <https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/racial-ethnic-disparities/index.html>.

¹⁹ See “The Costly Effects of an Outdated Organ Donation System: Foreword,” BLOOM WORKS (Oct. 2020), available at <https://bloomworks.digital/organdonationreform>.

²⁰ See “Letter Urging Improvements to the U.S. Organ Procurement and Transplant System to Better Support Families and Save Lives, FAMILIES USA (Oct. 2020), available at <https://familiesusa.org/resources/letter-urging-improvements-to-the-u-s-organ-procurement-and-transplant-system-to-better-support-families-and-save-lives/>.

²¹ See “FreedomWorks Statement in Response to Recent Rule Change Regarding Organ Procurement Organizations” FREEDOM WORKS (Nov. 2020), available at <https://www.freedomworks.org/content/freedomworks-statement-response-recent-rule-change-regarding-organ-procurement-organizations>.

²² See “The Trump administration’s organ donation efforts will save lives, Nobel Laureate Al Roth” CNN, available at <https://www.cnn.com/2019/07/10/opinions/trump-administration-crucial-step-organ-donation-roth-segal/index.html>.

²³ U. S. Department of Health and Human Services Moves to Increase Patient Access to Kidney Transplant With Transparency and Accountability for the Nation’s 58 Organ Procurement Organizations, AMERICAN SOCIETY OF NEPHROLOGY (Dec. 2020), available at https://www.asn-online.org/about/press/releases/ASN_PR_20201203_20.12.3_OPO_CFC_Pre.pdf.

²⁴ See Letter from equity researchers to Secretary-Nominee Becerra (Dec. 2020), available at https://58425eca-649a-42d4-b265-d1e1743b6c48.filesusr.com/ugd/581bc3_e70640160570491b9855d21980e87092.pdf.

²⁵ Karp, Seth, et al. “Fixing Organ Donation: What Gets Measured, Gets Fixed” JAMA SURG (May 27, 2020), available at <https://jamanetwork.com/journals/jamasurgery/article-abstract/2765994?appId=scweb>.

Committee²⁶ and the House Committee on Oversight and Reform’s Subcommittee on Economic and Consumer Policy²⁷ into several aspects of the U.S. transplant system.

We understand implementation of this rule has been delayed as part of a routine review of agency regulations, guidance, and other agency actions taken by the previous administration. We encourage the Biden-Harris Administration to implement the rule expediently once the agency-wide review is complete. This rule is urgent as it would make long overdue improvements to the organ transplant system that will save lives and improve health equity. Thank you for your attention to this important issue.

Sincerely,



Ron Wyden
Chairman
Committee on Finance



Charles E. Grassley
Member
Committee on Finance



Benjamin L. Cardin
Member
Committee on Finance



Todd Young
Member
Committee on Finance



Carolyn Maloney
Chairwoman
House Committee on
Oversight and Reform



James Comer
Ranking Member
House Committee on
Oversight and Reform

²⁶ See “Finance Committee Members Probe U.S. Organ Transplant System” S. COMM. ON FINANCE (Feb. 12, 2020), available at <https://www.finance.senate.gov/chairmans-news/finance-committee-members-probe-us-organ-transplant-system>.

²⁷ See “Oversight Subcommittee Launches Investigation into Poor Performance, Waste, and Mismanagement in Organ Transplant Industry, S. COMM. ON FINANCE US HOUSE COMM. ON OVERSIGHT AND REFORM (Dec. 23, 2020), available at <https://oversight.house.gov/news/press-releases/oversight-subcommittee-launches-investigation-into-poor-performance-waste-and>.



Raja Krishnamoorthi
Chairman
Subcommittee on Economic
and Consumer Policy



Michael Cloud
Ranking Member
Subcommittee on Economic
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Katie Porter
Member
House Committee on
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Tom Reed
Member of Congress
Co-Chair, Diabetes Caucus