

Congress of the United States
House of Representatives
Washington, DC 20515–0545

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Acting Secretary Cochran and Associate Director for Health Spiro,

We write to you today in support of the Center for Medicare and Medicaid Services rule issued on November 20, 2020: Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F.¹ We understand that you must conduct a thorough review of many midnight regulations issued by the Trump Administration. As longtime advocates for these reforms, we warn you that any delay in this rule’s implementation will cost patients’ their lives. While the rule’s implementation is now delayed until March 30 to give agency officials “the opportunity for further review of the issues of fact, law, and policy raised by this rule,”² we request that it be implemented rapidly after this review period. We strongly believe that this critically important and well-designed rule should be enforced as urgently and strongly as possible given the lives and equity implications at stake.³

OPOs were established under the National Organ Transplant Act in 1984. This legislation also created the national Organ Procurement and Transplantation Network (OPTN), which is responsible for managing oversight of OPOs. The United Network for Organ Sharing “serves as the OPTN under contract with the Health Resources and Services Administration.”⁴ There are currently 57 OPOs, each “operating as an unchecked regional monopoly,”⁵ and performance levels across OPOs are highly variable. According to research conducted by HHS itself, OPOs are failing to recover or transplant thousands of organs each year. This results from various problems, ranging from financial impropriety⁶ to quality control issues—including leaving transplantable organs on commercial flights⁷—to failure to hire enough staff to respond to all donation cases.⁸ In conducting research for the rule proposed in November, HHS even found that OPOs may be choosing not to pursue

¹ Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F, Centers for Medicare and Medicaid Services, Retrieved at: <https://www.cms.gov/files/document/112020-opo-final-rule-cms-3380-f.pdf>

² 42 CFR Part 486, [CMS-3380-F2], RIN 0938-AU02, Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Public Comment Period; Delay of Effective Date, Centers for Medicare and Medicaid Services, Retrieved at: <https://public-inspection.federalregister.gov/2021-02180.pdf>

³ Centers for Medicare and Medicaid Services, as cited.

⁴ Organ Procurement and Transplantation Network. U.S. Department of Health and Human Services, Retrieved at: optn.transplant.hrsa.gov/governance/about-the-optn

⁵ Reforming Organ Donation in America, The Bridgespan Group, Retrieved at: www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf

⁶ Taxpayers Help Pay for Organ Donor Groups’ Parties, Rose Parade Expenses, Trib Live, Retrieved at:

<https://archive.triblive.com/local/pittsburgh-allegheeny/taxpayers-help-pay-for-organ-donor-groups-parties-rose-parade-expenses/>

⁷ How Lifesaving Organs For Transplant Go Missing In Transit, Kaiser Health News, Retrieved at: https://khn.org/news/how-lifesaving-organs-for-transplant-go-missing-in-transit/?utm_source=STAT%20Newsletters&utm_campaign=06e49f9ea7-MR_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-06e49f9ea7-149550985&twitter_impression=true

⁸ Underperforming in New York: Nonprofit struggles to recover transplantable organs, Washington Post, Retrieved at: https://www.washingtonpost.com/national/underperforming-in-new-york-nonprofit-struggles-to-recover-transplantable-organs/2018/12/20/55475aea-fa5c-11e8-863c-9e2f864d47e7_story.html

procurement of organs from single-organ donors because they are evaluated on the number of organs procured per donor.⁹ This central concern of OPO mismanagement, lack of accountability, and metrics-gaming¹⁰ is what the previous Administration successfully worked to address in the final rule issued in November. This rule, building on work begun under the Obama-Biden Administration,¹¹ is projected to save more than 7,000 lives¹² every year, disproportionately lives of patients of color. It will also reduce costs to taxpayers, decreasing dialysis costs to Medicare by well over \$1 billion annually.¹³ We were proud to fight for this rule and we are committed to its future.¹⁴

The continuity of this rule aligns strongly with the Biden Administration's commitment to creating health equity.¹⁵ OPOs have been shown to engage in racial profiling and to otherwise provide wildly different service to Black patients and other patients of color, including failing to respond to cases involving Black patients, and treating Black families with less care and compassion as white families.¹⁶ This has resulted in a deeply inequitable system in which patients of color are far more likely to need organ transplants, and yet are far less likely to receive them.¹⁷ As Ben Jealous, past President of the NAACP wrote regarding this rule: "Astoundingly, many OPOs are calling for further delay of the new regulations, which would consign thousands of patients—mostly patients of color—to unnecessary death. If we understand the problem and know the solution, to withhold its implementation is cruel and senseless."¹⁸

Further, because COVID-19 ravages organs and is highly likely to increase the need for organ transplants, these reforms are more urgent than ever. As nephrologists have noted, "The next epidemic will be chronic kidney disease in the U.S. among those who recovered from the coronavirus. Since the start of the coronavirus pandemic we have seen the highest rate of kidney failure in our lifetimes. It's a long-term health burden for patients, the medical community -- and the

⁹ Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization, Centers for Medicare and Medicaid Services, Retrieved at: <https://www.hhs.gov/sites/default/files/cms-3380-p-ofr.pdf> and Changing Metrics of Organ Procurement Organization Performance in Order to Increase Organ Donation Rates in the United States, American Journal of Transplant, Vol. 17, Issue 12, Retrieved at: <https://onlinelibrary.wiley.com/doi/full/10.1111/ajt.14391>

¹⁰ 11,000 American Patients Will Die This Year Waiting for Transplants, New York Times, Retrieved at: <https://www.nytimes.com/2019/06/11/opinion/organ-transplant-deaths.html>

¹¹ FACT SHEET: Obama Administration Announces Key Actions to Reduce the Organ Waiting List, The White House, Retrieved at: <https://obamawhitehouse.archives.gov/the-press-office/2016/06/13/fact-sheet-obama-administration-announces-key-actions-reduce-organ>

¹² Final Rule, Centers for Medicare & Medicaid Services (CMS), HHS. Retrieved at: <https://www.cms.gov/files/document/112020-opo-final-rule-cms-3380-f.pdf>

¹³ New Federal Reform Will Boost Organ Transplants, Saving Thousands of Lives, Arnold Ventures, Retrieved at: <https://www.arnoldventures.org/stories/reform-by-u-s-department-of-health-and-human-services-will-boost-organ-transplants-saving-thousands-of-lives>

¹⁴ @RepKatiePorter, Twitter, Retrieved at: <https://mobile.twitter.com/RepKatiePorter/status/1341905839469150208>.

¹⁵ Executive Order On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, Executive Office of the President, Retrieved at: <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/> and Executive Order on Ensuring an Equitable Pandemic Response and Recovery, Executive Office of the President, Retrieved at: <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/21/executive-order-ensuring-an-equitable-pandemic-response-and-recovery/>

¹⁶ The Costly Effects of an Outdated Organ Donation System: Inequity in Organ Donation, Bloom, Retrieved at: <https://bloomworks.digital/organdonationreform/Inequity/>

¹⁷ The Costly Effects of an Outdated Organ Donation System: Inequity in Organ Donation, Bloom, Retrieved at: <https://bloomworks.digital/organdonationreform/Inequity/>

¹⁸ New Organ Donation Rule Is A Win For Black Patients And Health Equity, Health Affairs, Retrieved at: <https://www.healthaffairs.org/doi/10.1377/hblog20201211.229975/full/>

U.S. economy.”¹⁹ We must move urgently to implement OPO reforms today to serve COVID-19 survivors tomorrow.

Urgent implementation of this rule has been called for by every major patient group engaged on this issue, bipartisan leaders in the House²⁰ and the Senate²¹, all five former Chief Technology Officers at the Department of Health and Human Services (including all three who served under President Obama)²², leading data scientists²³, and national philanthropies²⁴, as well as the editorial boards of the Washington Post²⁵ and the New York Times²⁶, which noted that “an astounding lack of accountability and oversight in the nation’s creaking, monopolistic organ transplant system is allowing hundreds of thousands of potential organ donations to fall through the cracks.”²⁷

OPOs are currently under separate Congressional investigations from the House Committee on Oversight and Reform²⁸ and the Senate Finance Committee²⁹ into severe mismanagement, fatal lapses in patient safety³⁰, conflicts of interest³¹, and bad-faith, anti-patient lobbying³², including potentially accepting tens of millions of dollars in COVID-19 small business loans despite massive cash reserves. We understand, despite Congressional investigations and scrutiny, that OPOs and their trade association, the Association of OPOs (AOPO), are continuing to lobby to undermine these pro-patient, bipartisan reforms. Having engaged with this industry for the past two years, we feel a duty of care to relay that for too long contractors have skirted basic accountability in patients’ interests.

¹⁹ High odds severe Covid-19 can lead to kidney injury or failure, medical studies reveal, CNBC, Retrieved at: <https://www.cnbc.com/2020/08/03/severe-covid-19-can-lead-to-kidney-failure-medical-studies-reveal.html>

²⁰ Letter from Rep. Rose to Secretary Azar about Organ Procurement Organizations, Retrieved at: https://58425eca-649a-42d4-b265-d1e1743b6c48.filesusr.com/ugd/581bc3_a34641941c3e4dad86c015f019ba2051.pdf

²¹ Wyden Statement on Reforms to Organ Donation and Procurement Standards, US Senate Committee on Finance, Retrieved at: <https://www.finance.senate.gov/ranking-members-news/wyden-statement-on-reforms-to-organ-donation-and-procurement-standards>

²² The Costly Effects of an Outdated Organ Donation System: Foreword, Bloom, Retrieved at: <https://bloomworks.digital/organdonationreform>

²³ Fixing Organ Donation: What Gets Measured, Gets Fixed, JAMA Surg, Retrieved at: <https://jamanetwork.com/journals/jamasurgery/article-abstract/2765994?appId=scweb>

²⁴ A Statement From Arnold Ventures on Organ Donation Rules, Arnold Ventures, Retrieved at:

<https://www.arnoldventures.org/newsroom/a-statement-from-arnold-ventures-on-organ-donation-rules>

²⁵ Many die waiting for organs. The Trump administration could help, The Washington Post, Retrieved at: https://www.washingtonpost.com/opinions/many-die-waiting-for-organs-the-trump-administration-could-help/2020/07/31/77e3a102-dfd6-11e9-b199-f638bf2c340f_story.html

²⁶ She Beat Cancer. Now, She’s in Another Fight for Her Life, The New York Times, Retrieved at: <https://www.nytimes.com/2019/08/20/opinion/erika-zak-organ-donor.html>

²⁷ New York Times, as cited.

²⁸ Oversight Subcommittee Launches Investigation into Poor Performance, Waste, and Mismanagement in Organ Transplant Industry, US House Committee on Oversight and Reform, Retrieved at: <https://oversight.house.gov/news/press-releases/oversight-subcommittee-launches-investigation-into-poor-performance-waste-and>

²⁹ Grassley, Finance Committee Members Continue Investigation into U.S. Organ Transplant System, US Senate Committee on Finance, Retrieved at: <https://www.finance.senate.gov/chairmans-news/grassley-finance-committee-members-continue-investigation-into-us-organ-transplant-system>

³⁰ He died when he got the wrong lungs. It wasn’t the only organ error in SC that day, The Post and Courier, Retrieved 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

³¹ Mid-America Transplant Services and its officials move into for-profit ventures, St. Louis Post-Dispatch, Retrieved at: https://www.stltoday.com/business/local/mid-america-transplant-services-and-its-officials-move-into-for/article_f37bb65b-f000-5bf7-bc00-097b2f6341f5.html

³² Heartless: Organ Donation Contractors Lobby Against a Popular Health Care Initiative While Pocketing Pandemic Relief Loans, POGO, Retrieved at: <https://www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/>

We urge you to move forward not only with enforcing the newly finalized metrics, but with additional reforms to OPO oversight, transparency, accountability, and finances given the equity implications of both COVID-19 and the broken status quo in those communities who are often not served in the current organ donation system. Given this, we applaud HHS's decision, announced on January 15, 2021, to transfer the Division of Transplantation out of the Health Resources and Services Administration (HRSA) and into the Office of the Assistant Secretary for Health (OASH), in line with calls from patient advocates and racial equity leaders to centralize OPO oversight into an Office of Organ Policy.^{33,34}

Very Truly Yours,



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³³ New Organ Donation Rule Is A Win For Black Patients And Health Equity, Health Affairs, Retrieved at: <https://www.healthaffairs.org/doi/10.1377/hblog20201211.229975/full/>

³⁴ The Costly Effects of an Outdated Organ Donation System: Oversight Gaps and Conflicts, Bloom, Retrieved at: <https://bloomworks.digital/organdonationreform/Oversight/>