

Congress of the United States
Washington, DC 20515

July 19, 2021

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

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Secretary Becerra and Administrator Brooks-LaSure:

We write today to applaud the Administration for proceeding with the Centers for Medicare & Medicaid Services' (CMS) final rule entitled "Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations" ("Final Rule")¹ and to ask CMS to explore additional ways to accelerate the accountability of organ procurement organizations (OPOs). The COVID-19 pandemic is exacerbating the need for organs now and creating an urgent health equity issue, as communities of color are disproportionately impacted by the failures of the current organ donation system and the effects of COVID-19.

Reforming the U.S. transplant system is a bipartisan issue and we commend the Department for its recent implementation of this rule. Its enactment is the culmination of years of work by the Trump and Biden Administrations, with bipartisan support from both chambers of Congress, representing an unprecedented bipartisan effort.² The Final Rule takes long overdue steps to hold

¹ Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations, 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-medicare-programs-organ-procurement-organizations-conditions-for-coverage-revisions-to>.

² Senate Finance Committee Press Release (March 16th, 2021), available at <https://www.finance.senate.gov/chairmans-news/bipartisan-bicameral-members-of-congress-urge-biden-administration-to-finalize-organ-procurement-reforms>.

OPOs accountable, which marks critical progress towards improving the organ transplant system. However, in its current form, the Final Rule would not provide for the decertification of failing OPOs until calendar year 2026, even though CMS has published data since 2019 on which OPOs are underperforming, and quantified that thousands of lives are at stake each year.³ We are concerned about this protracted timeline for enforcement of the Final rule, because the COVID-19 pandemic is exacerbating the need for transplants now. Therefore, we encourage CMS to consider ways to hold OPOs accountable during this interim timeframe. It is critical that with lives at stake and disproportionate impacts on communities of color, OPOs not be allowed to continue to fail until 2026.

In November 2020, a bipartisan group of Congressional offices endorsed CMS's issuance of this rule, noting that its implementation could help save thousands of lives each year. In March of this year, a number of us also wrote a letter in strong support of this rule when its implementation was temporarily delayed in accordance with the Biden Administration's "Regulatory Freeze Pending Review" (86 FR 7814).⁴ At that time, we urged the Administration to proceed with the Final rule, citing the importance of reforming the standards to which OPOs are held accountable. On March 30, 2021, CMS enacted the Final rule, an action applauded by our offices.⁵

This Final Rule marks a critical first step toward ensuring greater accountability of all 57 OPOs in the United States. Since 2015, an average of more than 12,000 people have died each year while waiting for a transplant or were removed from the waiting list due to becoming too sick to undergo transplantation.⁶ According to data from the Department of Health and Human Services (HHS) the changes made by the Final Rule will address systemic problems and have the potential to save more than 7,000 lives every year.⁷ The U.S. Government Accountability Office 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,

³ 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-medicaid-programs-organ-procurement-organizations-conditions-for-coverage-revisions-to>; Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization, Proposed Rule 84 Fed. Reg. 70628 (published Dec. 23, 2019) (42 C.F.R. Part 486), available at <https://www.federalregister.gov/documents/2019/12/23/2019-27418/medicare-and-medicaid-programs-organ-procurement-organizations-conditions-for-coverage-revisions-to>.

⁴ Senate Finance Committee Press Release (March 16th, 2021), available at <https://www.finance.senate.gov/chairmans-news/bipartisan-bicameral-members-of-congress-urge-biden-administration-to-finalize-organ-procurement-reforms>.

⁵ Senate Finance Committee Press Release (April 8th, 2021), available at <https://www.finance.senate.gov/chairmans-news/wyden-and-grassley-applaud-biden-administration-for-beginning-to-implement-organ-procurement-reforms>.

⁶ 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>.

⁷ 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-medicaid-programs-organ-procurement-organizations-conditions-for-coverage-revisions-to>.

and objective outcome measures” and increase competition for control of open organ donation service areas.⁸ Reforming these standards to which OPOs are held was an important first step in improving the organ transplant system, though failure cannot be allowed to continue given the human cost of unaccountable and underperforming OPOs. As Ben Jealous, past president of the NAACP, wrote in favor of urgent enforcement of OPO decertifications, “If we understand the problem and know the solution, to withhold its implementation is cruel and senseless.”⁹

The need to act has only increased over the last 18 months. Some experts project a dramatic increase in the demand for transplants as a result of the COVID-19 pandemic because the virus can cause organ failure in survivors, particularly damage to the kidneys.¹⁰ Furthermore, transplants that were once a rarity, double lung transplants, are now becoming frequent transplant surgeries because COVID-19 survivors are often left with “destroyed” lungs, needing a new pair to survive.¹¹ As the demand for more organs and the need for advanced transplants continues to evolve, the transplant system must be improved to meet the needs of all patients.

Furthermore, as we noted in our previous letter, these reforms have urgent health equity implications. The failures of the current organ donation system disproportionately hurt patients of color.¹² 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 patients, they are much less likely to receive them than clinically similar white patients.¹³ As mentioned above, experts project a dramatically increased need for transplants as a result of COVID-19,¹⁴ which is likely to compound the disparities already experienced by minority populations.¹⁵ The reforms implemented in the Final Rule have important implications for improving health equity and should be considered an urgent step as the Administration continues to respond to COVID-19.

⁸ GOV'T ACCOUNTABILITY OFFICE, File B-332771 (Dec. 16, 2020), available at <https://www.gao.gov/products/B-332771>.

⁹ 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/>

¹⁰ Sperati, Christopher. “Coronavirus: Kidney Damage Caused by COVID-19,” JOHNS HOPKINS MEDICINE (Mat 14, 2020), available at <https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/coronavirus-kidney-damage-caused-by-covid19>.

¹¹ *Covid Spawns ‘Completely New Category’ of Organ Transplants*, KHN, Apr. 13, 2021, available at <https://khn.org/news/article/covid-spawns-new-category-of-organ-transplants/>.

¹² 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.”), available at <https://bloomworks.digital/organdonationreform/Inequity/>.

¹³ 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/>.

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

¹⁵ 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>.

In light of this urgent need, we are concerned about the protracted timeline for enforcement of the OPO rule, which currently does not allow for the decertification of failing OPOs until calendar year 2026.¹⁶ The enforcement of this rule is imperative and COVID-19 makes its implementation that much more critical. We thank the administration for moving forward with this rule, and ask you to consider additional ways to accelerate its impact to put patients' interests first, saves lives and reduce racial health disparities. Thank you for your attention to this important matter.

Sincerely,



Ron Wyden
Chairman
Committee on Finance



Chuck E. Grassley
Member
Committee on Finance



Todd Young
Member
Committee on Finance



Benjamin L. Cardin
Member
Committee on Finance



Joni Ernst
United States Senator



Michael F. Bennet
Member
Committee on Finance



Jerry Moran
United States Senator

¹⁶ 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-medicare-programs-organ-procurement-organizations-conditions-for-coverage-revisions-to>.



Carolyn B. Maloney
Chairwoman
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