

The American Civil Liberties Union (ACLU) believes that health care is a civil rights issue, and noting the [disparities](#) in organ donation both in treatment of prospective donors and patients awaiting transplant, agrees with bipartisan Congressional leaders that accelerating accountability for the government's own organ contractors is an "[urgent health equity issue.](#)"

Patients – and [disproportionately patients of color](#) and [patients with disabilities](#) – have too long been failed, and would be best served through increased accountability, transparency, and nondiscrimination from both organ procurement organizations (OPOs) and transplant centers. Additionally, basic principles of competition should be in place for federal contractors tasked with organ donation activities, including both OPOs and the organ procurement transplantation network (OPTN).

Given the lives at stake, OPO conditions for coverage (CfCs) and transplant center conditions for participation (CoPs) should reflect the priorities of the President's [Executive Order On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government](#). And given that [COVID](#) damages organs, we note that equity reforms in organ donation, particularly with regards to the governments' own contractors, are critical to the [Executive Order on Ensuring an Equitable Pandemic Response and Recovery](#).

As Medicare is payer for much of the OPTN, and OPTN failures harm patients, the ACLU also supports calls from the [House Appropriations Committee 2021 report](#) for the upcoming OPTN contract to be competitive for the first time, noting the [bipartisan Senate Finance Committee](#) investigation into "serious concerns related to UNOS' role in overseeing our nation's OPOs, which have been severely underperforming for decades."

Answers to specific questions follow.

The American Civil Liberties Union

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Solicitation of Public Comments

Are there revisions that can be made to the transplant program CoPs or the OPO CfCs to reduce disparities in organ transplantation? (pg 68599)

Transplant Center CoPs

(also related to Question 5, pg 68599: What changes can be made to the current requirements to ensure that transplant programs ensure equal access to transplants for individuals with disabilities?)

As noted in the RFI, "[a] 2019 National Council on Disability report found that people with disabilities are frequently denied equal access to receive organ transplants based solely on their disability status." Individuals with disabilities have historically been denied lifesaving organ

transplants based on assumptions that their lives are less worthy, that they are incapable of complying with post-transplant medical regimens, or that they lack adequate support systems to ensure compliance. A [2008 Stanford University survey](#) of 88 transplant centers found that 85% of pediatric transplant centers consider neurodevelopmental status as a factor in their determinations of transplant eligibility at least some of the time.

As HHS has noted, “Section 504 of the Rehabilitation Act of 1973 is a national law that protects qualified individuals from discrimination based on their disability... [and] forbids organizations and employers from excluding or denying individuals with disabilities an equal opportunity to receive program benefits and services.”

Following Section 504, no transplant programs should be able to exclude prospective transplant recipients on the basis of disability. And in considering the potential for a prospective transplant patient’s success, [reasonable modifications must be considered](#), a point made by HHS’ Office of Civil Rights. These reasonable modifications include the support systems that are in place - or could be put in place - to assist with post-transplant medical regimens. Any individuals who believe they have been discriminated against should be able to bring a claim to HHS OCR for expedited review and resolution.

Additionally, per earlier comments shared with HHS OCR:

- HHS OCR should issue guidance clarifying transplant center and physician obligations regarding organ transplantation under Section 504 and the ADA.
- Given the time-sensitive nature of health care discrimination against people with disabilities, especially where it involves the denial of life-sustaining treatment, HHS OCR should launch a hotline, coupled with an expedited priority enforcement process, for disability discrimination in health care, placing particular (though not exclusive) emphasis on the withdrawal of life-sustaining treatment.
- Working with HRSA and OPTN, HHS OCR should provide ongoing technical assistance to transplant centers on their obligations under the ADA and Section 504.

OPO CfCs

CMS should include within OPO CfCs that equitable procurement is part of what is required for tier 1 (passing) status, as well as to be a heavily weighted factor in the event multiple OPOs bid for the same Designated Service Area.

Among the inequities patients of color face in the organ transplantation process is failure of many OPOs to fairly and equitably treat the families of donors of color. [Research](#) shows OPOs are [only 50 percent as likely](#) to talk to the family of a Black donor as that of a white donor; and that when they do they [spend less time](#) with them and respond with [less compassion](#).

This inequitable performance has deadly consequences, both in a lower number of organs procured and transplanted (which directly translates to preventable deaths) and in higher deaths of patients of color on the waiting list.

Additionally, to understand breakdowns in equitable treatment of both donor families and patients throughout the process, CMS should require all OPO process data be made available, in line with the [commitment](#) of seven OPOs that was highlighted by bipartisan leaders of the [House Oversight hearing on May 4th 2021](#). After such data reporting is required, CMS can also update the definition of “Urgent Need” to include that CMS can invoke urgent need to decertify any OPO at any time if there is a meaningful discrepancy in its response rates, including response times, for donors of color compared with white donors.

Are there additional factors or criteria that CMS should consider when determining which OPO should be selected for an open service area? (pg 68601)

Independent of CMS’ specific outcome measures, what other metrics or attributes reflect a model or highest performing OPO? (pg 68601)

What are quantitative or qualitative indicators of excellent performance and how can CMS incorporate these with outcome measures when assessing OPOs for recertification purposes? (pg 68601)

A proven track record of equitable procurement of organs should also be considered in determining which OPO should be selected for an open service area; is part of what should reflect a model or high performing OPO; and is critical to excellent performance. (See previous comments.)

Analysis of CMS data shows a [10-fold variability](#) across OPOs in their service of Black communities, including that some OPOs qualifying for tier 1 status in 2019 were among the worst OPOs in serving Black donors. No OPO should be allowed to maintain certification if procurement is inequitable in its performance across racial and ethnic groups.

Should CMS consider additional metrics, such as those that measure equity in organ donation or an OPO’s success in reducing disparities in donation and transplantation, and how should this be measured? (68601)

An OPO’s success in reducing disparities in donation and transplantation through equitable procurement of organs should be considered. This can be measured in the same dataset CMS uses now for certification, simply including a data cut based on race/ethnicity. (See previous comments.)

Should CMS consider other performance measures when selecting an OPO for an open DSA? Such measures could include performance on converting donor referrals to potential donors or

the number of “zero organ donors” or the number of organ discards (see section C.5. for additional information), reflected in the discard rate, or improvement, over time. (pg 68601)

Per existing CfCs, no credit should be given for “zero organ donors” as they do not result in any lives saved, and could result in gaming of the system and further inequity. Similarly, organs for research which could be used to game the system should not be counted (per questions on “organs for research”).