

Centers for Medicare and Medicaid Services Performance Metrics and the Disproportionate Impact of Decertifying Organ Procurement Organizations on Minority Populations

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In its Final Rule on November 20, 2020, the Centers for Medicare and Medicaid Services (CMS) introduced new Organ Procurement Organization (OPO) performance evaluation metrics with the stated goal of increasing organ donation and ensuring accountability across the 55 federally designated OPOs in the United States.¹ These metrics classify OPOs into 3 tiers based on donation and transplantation rates, with tier 1 programs automatically recertified, tier 2 programs required to compete, and tier 3 programs automatically decertified. The first round of OPO decertification will occur in 2026, based on 2024 performance assessments.

Although the emphasis on performance is laudable, the CMS metrics have important limitations, as noted during the intense 23-mo CMS public comment period by the Scientific Registry of Transplant Recipients and by notable statisticians and health services researchers.¹⁻⁸ One limitation is that the current framework may unintentionally penalize OPOs serving racially and ethnically diverse communities, where structural inequities, historical mistrust, and lower donor registration rates are prevalent.^{9,10} As a result, the CMS metrics and subsequent OPO decertification process may exacerbate existing inequities in donation and transplantation, rather than reduce them. In this Expert Insight article, we present quantitative evidence linking projected OPO tier assignment with racial and ethnic composition of donation service areas (DSAs) and discuss implications for system performance, public trust in organ donation, and equity.

We projected CMS tier designations for all 55 OPOs based on their 2024 (from January 1, 2024, to December 31, 2024) performance using the same data sources and calculation methods used by CMS.¹ Numerators consisted of the number of CMS-defined organ donors and organs transplanted per OPO, obtained from the United Network for Organ Sharing. Denominators, representing

each OPO's donor potential, were derived from mortality data available through the Centers for Disease Control and Prevention WONDER datafile (<https://wonder.cdc.gov/>). The 2024 tier thresholds for CMS donation and transplantation measures were determined on the basis of the performance of all OPOs in the prior year (2023) using the same data sources and methodology described earlier. During the past 3 y, our projected OPO tier placements, based on these thresholds, have matched the final tier placements published by CMS 97% of the time.

To evaluate the association between DSA racial/ethnic composition and projected tier status, we conducted an ordinal logistic regression (proportional-odds cumulative logit model), treating tier 1 through tier 3 as ordered categories. Population composition for each DSA was calculated using US Census Bureau's 2023 American Community Survey data,¹¹ expressed as the proportion of residents identifying as White, Black, Hispanic, or other race. To account for the unit-sum constraint, we included K-1 proportions in the model, omitting % White as the reference category. Effects were scaled by 10-percentage-point (pp) increases in population share and expressed as odds ratios (ORs) with 95% confidence intervals (CIs). Goodness-of-fit was assessed using the likelihood-ratio test, pseudo-R², and proportional-odds assumption testing.

Figure 1 shows the racial/ethnic composition of the population served by OPOs in each of the 3 CMS tiers. The aggregate percentage of the non-White population served by OPOs in each of the 3 CMS tiers is as follows: 31.9% in tier 1, 41.0% in tier 2, and 57.0% in tier 3. Analysis showed that the model fit was acceptable (Nagelkerke R² = 0.36; Pearson P = 0.35; Deviance P = 0.73), indicating good explanatory value. Results demonstrated significant, independent associations between DSA racial/ethnic composition and OPO tier

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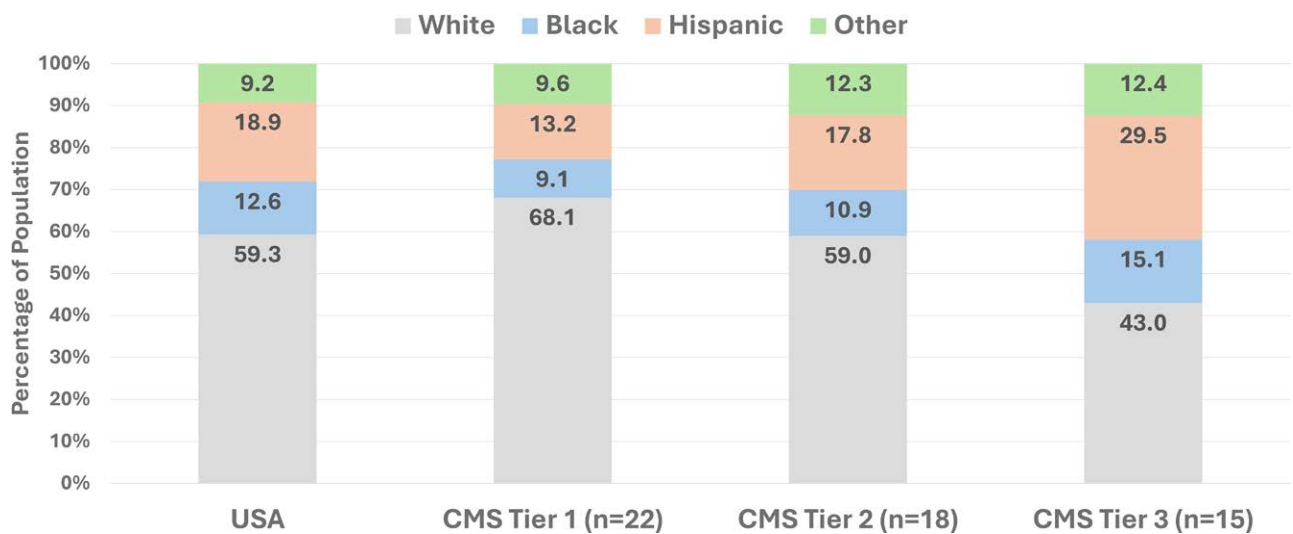


FIGURE 1. Race/ethnicity percentages of the population in United States and in donation service areas (DSAs) served by Organ Procurement Organizations (OPOs) based on projected CMS tier designation. CMS, Centers for Medicare and Medicaid Services.

assignment: Black population share (OR, 4.05 per +10 pp; 95% CI, 1.91-8.56; $P < 0.001$), Hispanic population share (OR, 1.91 per +10 pp; 95% CI, 1.30-2.81; $P = 0.001$), and other minority population share (OR, 2.08 per +10 pp; 95% CI, 1.06-4.09; $P = 0.03$). OPOs serving communities with larger proportions of Black, Hispanic, or Other Minority residents are significantly more likely than those serving mostly White populations to be placed in lower (worse) CMS tiers. Across the 55 OPOs, those projected to fall in tier 3 (automatic decertification) serve disproportionately high shares of non-White populations.

This analysis substantiates the concerns raised by others and further underscores the inherent flaws in the CMS performance metrics, including the failure to statistically adjust for race/ethnicity.^{4,6,7} The finding that OPOs serving diverse regions are more likely to be penalized aligns with long-recognized differences in donor registration and authorization by race and ethnicity. In 2023, for instance, donor registration among donation-eligible deaths is approximately 39% among White decedents compared with 21% among Black and 23% among Hispanic decedents.¹² Similarly, when the decedent was not a registered donor, next-of-kin authorization rates are substantially lower among minority families.¹³ These patterns most likely stem from deep-rooted social determinants, including historical abuses in medical research, distrust of institutions, and inequitable access to transplantation.^{9,14} OPOs operating in such environments often devote extensive resources to community engagement, bilingual staffing, and faith-based partnerships to deliver culturally tailored donation education, build trust, and improve authorization rates. Yet under CMS's unadjusted performance measures, some OPOs serving these multicultural communities appear to perform "below average," despite potentially achieving outcomes that exceed expectations given the contexts in which they operate.⁴

The potential service disruptions of decertification are numerous and far-reaching. Decertification triggers a federal rebid and a transition to a new OPO, which will necessitate renegotiation of hospital agreements,

reestablishment of electronic health record access, remapping of on-call and dispatch logistics, and merging of information technologies, quality programs, and clinical protocols. Moreover, although the Final Rule provides a broad structure of competition and takeover of tier 3 OPOs, the detailed mechanics are unknown, for example, bidding criteria, timeline for takeover, how hospitals/hospital contracts are transitioned, how donor networks and hospital agreements are handled, and how the loss of a highly skilled workforce in those decertified OPOs will be prevented, among others. Consider that OPOs projected to fall into tier 3, collectively in 2024 alone, had contracts with >1600 hospitals, managed >340 000 hospital referrals, and recovered and facilitated the transplantation of 11 181 organs from 4099 deceased donors.¹⁵ During the OPO decertification process to occur in 2026, declines in referral capture and organ recovery, which can translate into lost opportunities for patients awaiting transplantation, are highly plausible even if such transitions are well managed.

Communities of color already face a disproportionate burden of end-stage organ disease.⁹ The potential decertification of OPOs serving these communities risks compounding inequities by reducing local donation capacity precisely where transplant need is greatest. In 2024, 47% of all deceased donors in tier 3 OPOs were non-White (compared with only 26% in tier 1 OPOs), further highlighting the dependence of equitable access to donation legacy opportunity and transplantation on the stability and strength of these organizations.

At its core, organ donation relies on trust earned by OPOs among critical care teams, medical examiners, motor vehicle department staff, community leaders, local and state government officials, the public, and, of course, families grieving the imminent death of a loved one. Decertification is likely to disrupt these relationships and may lead to the dismantling of culturally specific outreach networks that took years to build. For many OPOs serving diverse populations, bilingual or culturally concordant staff are essential to public education, donor family communication, and aftercare for donor families.

Attrition among these experienced staff during decertification can erode community trust and lead to downstream reduction in donor registry enrollment, donation authorization rates, and the availability of transplantable organs.

We agree that transparency and high expectations for improvement are necessary ingredients for ensuring public trust in donation and transplantation. However, this must be achieved through valid and reliable performance standards that capture the complexities of the populations served by OPOs. The Final Rule assumes that all OPOs operate in demographically comparable environments, an empirically untenable assumption that poses a heightened risk of unintended harm. The variation in DSA racial/ethnic composition and its strong association with CMS tier status suggest that OPO performance metrics must be contextualized to prevent structural bias. Without adjustment, OPOs serving multicultural communities face a punitive cycle: lower measured performance leads to decertification, disruption weakens donation capacity, and inequities in donation and transplantation access widen further. Accountability and fairness are not competing goals; they are codependent. A balanced policy framework that recognizes contextual complexity while upholding rigorous performance standards is essential to ensuring that reforms designed to improve the system do not, in turn, deepen the inequities they seek to overcome.

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