ASAN
AUTISTIC SELF ADVOCACY NETWORK
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February 1, 2022

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3409-NC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Autistic Self Advocacy Network Re: Docket #CMS-3409-NC, RIN #0938-AU55, "Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities"

The Autistic Self Advocacy Network (ASAN)[1] appreciates the opportunity to provide feedback for the Centers for Medicare and Medicaid Services (CMS)' Request for Information (RFI)[2] on improving the United States' nationwide organ transplant and procurement network, particularly with respect to equity. ASAN is pleased that CMS is utilizing Medicare and Medicaid funding as an opportunity to reduce disparities and improve quality for the more than 39,000 transplant recipients and more than 100,000 people on waiting lists for organs.[3]

According to the National Council on Disability's 2019 report, people with disabilities, particularly those of us with the most significant cognitive disabilities and support needs, still have difficulty obtaining organ transplants due to prejudiced or mistaken assumptions about our quality of life and ability to comply with post-operative care.[4] Discrimination occurs even though most disabilities unrelated to the reason for transplant have no effect on transplant success.[5] ASAN therefore answers those questions posed by CMS which relate to discrimination and offers short recommendations for addressing it.

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[1] For more information on ASAN, visit our website at: https://autisticadvocacy.org/.

[2] Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities, 86 Fed. Reg. 68594, 68594 (Dec. 3, 2021)(to be codified at 42 C.F.R. Ch. IV).

[3] 86 Fed. Reg. at 68595.

[4] Nat'l Council on Disability, Organ Transplant Discrimination Against People with Disabilities 11 (Sept. 25, 2019), *available at* https://ncd.gov/sites/default/files/NCD_Organ_Transplant_508.pdf.

[5] *Id.* at 38-40 (discussing the impact of specific categories of disability on transplant, including that people with significant cognitive disabilities can undergo post-operative care successfully with a support system in place).

How can CMS meaningfully measure transplant outcomes without dis-incentivizing transplantation of marginal organs or dis-incentivizing performing transplants on higher risk patients?

CMS should avoid measures of transplant outcomes which explicitly discriminate on the basis of disability. For example, the use of Quality Adjusted Life Years (QALYs) is widely considered discriminatory, as QALYs often undervalue treatments that extend the lives of those with chronic illnesses and disabilities, which would include many organ transplant patients.[6] This occurs because the QALY attempts to merge quality of life improvements with life extension, but it bases valuation of "quality of life" on the extent to which a person becomes less disabled.[7] Therefore, if a treatment primarily extends the life of a person with a disability, as some classes of organ transplantation would, use of the QALY will undervalue it. We recommend instead that CMS base transplant outcome measures on the length of time that the organ functions as intended and on direct medical improvements to relevant organ functions, such as measurable improvement of lung function after a lung transplant.

If CMS chooses to measure quality of life, it should base its measures on those outcomes that are most significant to transplant patients. Value frameworks and measures exist or are being developed that measure patient-relevant outcomes, such as FasterCures' Patient Perspective Value Framework and some forms of multi-criteria decision-making.[8]

While ASAN cannot speak extensively on the subject of "marginal" donor organs, we caution against the use of any measures which would lead to high-risk patients receiving primarily lower-quality organs. These patients will improve the most readily when they receive high-quality organs early.

Are there revisions that can be made to the transplant program CoPs or the OPO CfCs to reduce disparities in organ transplantation? What changes can be made to the current requirements to ensure that transplant programs ensure equal access to transplants for individuals with disabilities?

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[6] *Id.* at 20.

[7] *See* Nat'l Council on Disability, Quality-Adjusted Life Years and the Devaluation of Life with Disability 26-31 (Nov. 6, 2019), *available at* https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf (explaining that most questionnaires used to calculate the QALY, such as the EQ-5D, base their health utilities on direct aspects of disability, such as being able to walk - some of which have no impact on subjective quality of life).

[8] *Id.* at 63, 64.

Conditions of Participation are rules that a transplant program must adhere to in order to remain eligible for Medicare or Medicaid. ASAN would be interested in revisions to Conditions of Participation (CoPs) that would bar eligibility for Medicare or Medicaid funding unless a transplant program can show that its evaluation procedure, whether formal or informal, does not discriminate on the basis of disability unless that disability has a direct medical impact on transplant success. Transplant centers could prove this by: (1) providing a written policy to CMS describing which conditions and circumstances are total or partial contraindications to which types of transplants; and (2) providing a written description of the center's typical evaluation process, including language prohibiting discrimination. Nondiscrimination language should include a discussion of reasonable modifications of the evaluation framework. CoP requirements for the transplant center's written patient selection criteria in particular should specify that the patient psychosocial evaluation cannot be used to discriminate solely on the basis of a mental health disability or intellectual disability.[9] Additionally, the requirements should specify that a patient who cannot independently comply with post-operative care should not be excluded from consideration if they could or can comply with adequate support.

Many Medicare and Medicaid recipients are people with disabilities, and thus such a rule if implemented would be likely to reduce disparities for prospective patients on Medicare and Medicaid. Several state laws already bar organ transplant discrimination of this kind.[10] However, a financial incentive for avoiding discriminatory policy may serve to reduce disparities further and create a nationwide standard.

We recommend that current data reporting requirements in the CoPs be revised to show the racial, ethnic, gender, and disability-related personal characteristics of patients who have received transplants, who have been placed on a waiting list, and who have been deemed ineligible for transplant waiting list placement, where such data does not violate the Health Insurance Portability and Accountability Act (HIPAA). For example, transplant centers could provide overall data on the number of patients placed on the waiting list who are Black, Indigenous People of Color (BIPOC) without revealing personal information.[11]

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[9] Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants; Final Rule, 72 Fed. Reg. 15198, 15276 (Mar. 30, 2007) (codified at 42 C.F.R. §§ 405, 482, 488, 498), https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/Downloads/trancenterreg2007.pdf.

[10] Nat'l Council on Disability, Organ Transplant Discrimination at 57-60.

[11] Department of Health and Human Services, Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, available at https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html

How can the CoPs/CfCs ensure that transplant programs, ESRD dialysis facilities, and OPOs distribute appropriate information and educate individuals in underserved communities on organ transplantation and organ donation?

People with disabilities are a notoriously underserved population, regardless of area, particularly BIPOC people with disabilities. ASAN recommends that the CoPs and/or Conditions for Coverage (CfCs), where they require the informed consent of patients,[12] be required to provide all information in a manner that is accessible to individuals with disabilities. This includes written information readable by screen reader, sign language interpretation, Braille, and other accessible print forms of documents for the Blind and visually impaired, and plain language or Easy Read versions of documents for people with cognitive disabilities. For more information on how to format a document so that it is plain language or Easy Read, consult ASAN's "One Idea Per Line: A Guide to Making Easy Read Resources" guide.[13]

What changes can be made to the current requirements to address implicit or explicit discrimination, such as decisions made based on faulty assumptions about quality of life and the ability to perform post-operative care?

We recommend the adoption of nondiscrimination requirements into existing CoPs/CfCs, as outlined above. We also recommend annual or biannual reviews by CMS of whether existing organ transplant centers are conforming to the requirements present in their CoPs. If a transplant center is found noncompliant, the transplant center should be required to revise their policies within six months to a year. Regular review for and enforcement of legal standards makes it less likely that eligible transplant centers and OPOs will fall out of compliance. Additionally, ASAN recommends that the CoPs require transplant physicians and nurses affiliated with the hospital, as well as affiliated specialists who help manage post operative care, to undergo an annual training describing the needs of people with intellectual and developmental disabilities during transplant and post-operative care, as well as clarifying that people with IDD can perform these tasks with support.

Independent of CMS' specific outcome measures, what other metrics or attributes reflect a model or highest performing OPO? Should CMS consider additional metrics,

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[12] *See, e.g.,* 72 Fed. Reg. at 15278 ("Transplant centers must implement written transplant patient informed consent policies…").

[13] *One Idea Per Line: A Guide to Making Easy Read Resources,* Autistic Self Advocacy Network, https://autisticadvocacy.org/resources/accessibility/easyread/ (last visited Jan. 24, 2022).

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?

ASAN recommends that CMS include as an outcome measure the degree to which an OPO successfully acquires informed consent from a diverse range of individuals. This outcome measure should also include the extent to which the OPO avoids promoting organ donation to those who are facing complex medical problems that might be complicated by the introduction of organ donation considerations, interfering with these patients' need to make choices about their care independent of coercion from others. As the National Council on Disability report on organ transplantation outlines, many disability rights organizations are concerned that OPOs may be aggressively "recruiting" for organ donation from terminally ill patients, survivors of recent severe injuries, and others with chronic untreatable conditions.[14] The interest of OPOs may influence decisions about continuation or withdrawal of life-sustaining care.[15] ASAN condemns this behavior and recommends that CMS directly address it through standards for OPOs. Additionally, we recommend that CMS consult with the Organ Procurement and Transplantation Network (OPTN) on whether it can provide guidance on obtaining informed consent from people with the most significant disabilities using frameworks such as supported decision-making.

Should a patient being placed on invasive mechanical ventilation, except for a planned medical or surgical procedure, be one of the triggers for a referral to the OPO?

ASAN strongly opposes any such trigger being created or used for OPO referrals. Such a referral is only more likely to reproduce discrimination by OPOs towards people with chronic and/or terminal illness, as well as people with disabilities that impact lung function. Many individuals with disabilities that impact lung function may have regular visits to the hospital that involve invasive medical ventilation but are nonetheless unlikely to result in imminent death. If we are to increase the supply of donated organs, it cannot be done at the expense of ethical obligations towards individuals with disabilities.

ASAN thanks CMS again for the opportunity to comment. For more information on ASAN's positions on organ transplantation please contact Kelly Israel, our Policy Analyst, at kisrael@autisticadvocacy.org.

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[14] Nat'l Council on Disability, Organ Transplant Discrimination at 33-34.

[15] *Id.*