July 10, 2020

The Honorable Alex Azar  
The Honorable Seema Verma
Secretary  
Administrator
Department of Health and Human Services  
Center for Medicare and Medicaid Services
200 Independence Avenue SW  
7500 Security Boulevard
Washington, DC 20201  
Baltimore, MD 21244

Dear Secretary Azar and Administrator Verma,

We write today with concerns regarding federal oversight of organ procurement organizations (OPOs), the non-profit entities that are granted federal approval to be the sole bodies responsible for procuring deceased-donor organs for transplantation in each region of the country. The Department of Health and Human Services (HHS) put out a Notice of Proposed Rule Making (NPRM) on December 17, 2019. This rule responded to many of the concerns that we raised when we first reached out to you in October of last year about the lack of oversight and reporting requirements for OPOs.

Unfortunately, OPOs are now asking that the accountability requirements that this rule would establish be deferred because of the COVID-19 pandemic. They are requesting the deferment of this rule, which would work to ensure that taxpayer dollars are being spent appropriately, while they are pursuing and receiving federal funds from various COVID-19 aid sources. We are concerned by these actions and by the OPOs lack of support for federal oversight measures during the greatest challenge our health care system has ever seen. We ask that you continue to move forward with the rule making process and establish clear and concise guidelines for OPOs.

As you know, OPOs were established under the National Organ Transplant Act (NOTA) 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 (UNOS) “serves as the OPTN under contract with the Health Resources and Services Administration (HRSA),” a division of HHS. As you noted in a June 30th response to an inquiry submitted by Rep. Porter in October 2019, CMS also has a role in oversight.

This fracturing of responsibilities between government agencies and a government contractor has led to calls from the New York Times editorial board to “revisit the UNOS monopoly” and from stakeholders to

streamline oversight responsibilities within HHS to ensure accountability.4 For this reason, we welcome the recent HHS Request For Information (RFI)5 as a critical first step in introducing much-needed competition into this contract, especially in light of recent reporting finding “a startling number of lifesaving organs are lost or delayed after being shipped on commercial flights, the delays often rendering them unusable” because UNOS relies on a “primitive system of phone calls and paper manifests, with no GPS or other electronic tracking required.”6

Nationally, there are 58 OPOs, each “operating as an unchecked regional monopoly,”7 and performance levels across OPOs are highly variable. Recently, the New York Times described the current OPO system as having an “astounding lack of accountability and oversight in the nation’s creaking, monopolistic organ transplant system”, which is “allowing hundreds of thousands of potential organ donations to fall through the cracks.”8 According to HHS itself, OPOs are failing to recover or transplant thousands of eligible organs, with more than half of all OPOs out of compliance on baseline performance measures.9 This is unacceptable. In fact, there may be up to 28,000 available organs from deceased donors annually which are not procured for transplantation. This results from various problems, ranging from financial imprropriety10 to quality control issues—including leaving transplantable organs on commercial flights11—to failure to hire enough staff to respond to all donation cases.12 In conducting research for the rule proposed in December, HHS even found that OPOs may be choosing not to pursue procurement of organs from single-organ donors because they are evaluated on the number of organs procured per donor.13,14 This central concern of OPO mismanagement, lack of accountability, and metrics-gaming15 is what you worked to address in your proposed rule.

As your June 30th letter noted, “since 2010, all OPOs out of compliance with a process measure made the necessary corrections to remain in the Medicare program.” Given how discordant this is with what the December 19th 2019 proposed rule showed—32 of 58 OPOs failing both proposed outcome measures—we note how broken the current outcome measures are, and encourage you to move forward with the appropriately patient-centered standards you proposed. Clearly, the existing standards do not meaningfully identify or allow CMS to address underperformance in the OPO industry, and, as such, we urge HHS to finalize its proposed rule as soon as possible this year. By way of your example on LiveOn

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4 Addressing the Organ Donor Crisis, Day One Project, Retrieved at: https://www.dayoneproject.org/post/addressingorganandonorcrisis
5 Modern National Resource Allocation System. This Request for Information (RFI) is issued by the Health Resources and Services Administration (HRSA) for the purpose of planning and market research only, Health Resources and Services Administration, Retrieved at: https://beta.sam.gov/opp/a06ffac2903c41629aad693753c2e6b7/view
13 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-3-3-80-p-ofr.pdf.
15 11,000 American Patients Will Die This Year for Transplants, New York Times, Retrieved at: https://www.nytimes.com/2019/06/11/opinion/organ-transplant-deaths.html
NY we note that, since this OPO was first flagged as underperforming, nearly 7,000 New Yorkers have been removed from the waiting list because they died or became too sick to transplant,\(^\text{16}\) not to mention the untold thousands more New Yorkers who were never even waitlisted because of this severe shortage. Patients do not have years to wait, and as the LiveOn NY example shows, there is no reason to have confidence that performance improvement plans actually lead to OPO improvement or better results for patients.

Given the urgency of implementing the proposed reforms, we are deeply concerned to learn that OPOs are now requesting that HHS delay finalization of the outcome measures until after the public health emergency. There is no reason to do so and, given the risks COVID poses to many patients in organ failure, it is all the more critical for HHS to move forward in finalizing and implementing the rule. Additionally, we note that AOPO has advocated that the December Proposed Rule not come into effect until the 2026 certification cycle. As HHS itself notes, even minimum compliance with proposed standards could lead to 5,000 organ transplants per year. We cannot consign 20,000 or more patients to die waiting for organ transplants while federal contractors are not held accountable, and therefore urge you to use the new standards in the next recertification cycle.

Further, we have concerns regarding the Association of Organ Procurement Organizations’ request for funds from the Provider Relief Fund. Under the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Congress established the $175 billion Provider Relief Fund, to support frontline health care providers.\(^\text{17}\) The Association of Organ Procurement Organizations wrote to HHS on April 30, 2020, explaining their reasoning for requesting that they be given funds:

> While OPOs are not designated as healthcare providers as defined by the CARES Act, they have been impacted by the pandemic and should benefit from these funds because the Congressional intent of the Act is to provide an influx of funds to the healthcare industry, which the federally regulated OPOs service. We would request a special exception for OPOs to receive funding from the discretionary portion of the budget that Congress did not specifically earmark.

While we understand that the income of OPOs may have decreased in recent months, these funds are intended to support those health care providers who are on the frontlines of this crisis, and whose revenues have plummeted in the wake of safety measures, increased equipment costs, and the suspension of elective procedures. This is not the case for OPOs, who may actually see an uptick in the number of organs available for procurement during the pandemic, as “deaths of despair”—i.e. deaths from suicide and substance use disorders—are tragically projected to increase dramatically as a second-order effect of the pandemic, including its impact on the economy.\(^\text{18}\) Additionally, many OPOs already have significant cash reserves,\(^\text{19}\) and some OPOs have established private foundations; given that these reserves are already built up using taxpayer dollars, bailout funding is inappropriate.

As we, and our colleagues on the Senate Finance Committee, have previously raised questions regarding OPO leadership’s salaries and the use of taxpayer funds that have gone unanswered, it is concerning that OPOs are now requesting access to these limited dollars. OneLegacy, the OPO serving Los Angeles and Orange Counties, compensates board members with taxpayer funds, including $100,000 annually to its Board Chair.\(^\text{20}\) The CEO of OneLegacy is paid $716,460 annually, and the CEO of Gift of Life, the

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\(^\text{16}\) Orange Procurement and Transplant Network, State Data, Health Resources and Services Administration, Retrieved at: https://optn.transplant.hrsa.gov/data/view-data-reports/state-data/

\(^\text{17}\) Public Law No: 116-136, Section 15011


\(^\text{19}\) Trib Live, as cited.

\(^\text{20}\) OneLegacy 990, 2017, Cause IQ, Retrieved at: https://www.causeiq.com/organizations/view_990/953138799/1ae469cf62e5bd30ce353e98fad67d165
highest compensated CEO of any OPO, is paid $2,519,902 annually. These are their reported salaries, but OPO executives may actually make far more than what is reported, including through private ventures which present the opportunity to reallocate taxpayer resources away from lifesaving activities, including with tissue processing facilities. While we hope that our OPOs are only hiring the best and brightest for these important positions, we also need to ensure that taxpayer dollars are not being used to line the pockets of wealthy board members and organization leadership, especially given that HHS has determined that more than half of all OPOs to be failing.

What we ask is that you continue to hold OPOs accountable during this critical and difficult time for our country. Given COVID poses additional risks to patients, this is of increasing urgency and importance. To do this, we must:

- Finalize the proposed standard set in the December 2019 NPRM, which found 37 of the 58 OPOs out of compliance on one or both performance measures, as soon as possible;
- Ensure the new outcome measures are used in the 2022 certification cycle; and
- Conduct appropriate review of taxpayer funds if provided to OPOs as part of required oversight.

We appreciate your attention to this important issue and your commitment to oversight and accountability of OPOs. We owe it to the more than 110,000 patients and growing who remain on the organ transplant waitlist to address this issue as quickly as possible.

Thank you, and we look forward to your response.

Best,

KATIE PORTER  KAREN BASS
Member of Congress  Member of Congress

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22 Mid-America Transplant Services and its officials move into for-profit ventures, St Louis Today, Retrieved at: https://www.stltoday.com/business/local/mid-america-transplant-services-and-its-officials-move-into-for/article_f37bb65b-f000-5bf7-bc00-097b2f341f5.html