October 7, 2019

The Honorable Alex Azar  
Secretary  
Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

The Honorable Seema Verma  
Administrator  
Center for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Secretary Azar and Administrator Verma,

I write today with serious concerns regarding federal oversight of organ procurement organizations (OPOs), the non-profit entities that are granted federal approval to be the sole body responsible for procuring deceased-donor organs for transplantation in each region of the country. I am concerned that the lack of rigorous oversight is putting patients’ lives at risk.

Recent reports suggest that thousands of usable organs are not reaching patients in need and that many OPOs — including OneLegacy, which serves my constituents in Orange County — engage in mismanagement and misuse of public funds, with little, if any, accountability from the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS).\(^1\) As you begin to implement President Donald Trump’s Executive Order requiring major improvements to our organ transplant system, I urge you to address the OPOs’ chronic underperformance and financial mismanagement by adjusting regulations, reporting requirements, and performance metrics in order to spur improved OPO outcomes; conducting more frequent and publicly accessible audits of OPOs financial management and general effectiveness; and reviewing why CMS has not used its authority to decertify any underperforming OPOs in 20 years.\(^2,3\)

**Transplant Need in the United States and the Role of Organ Procurement Organizations**

According to United Network for Organ Sharing (UNOS), as of September 8, 2019, there were 112,895 people in the United States on the waitlist for an organ transplant, but only 22,836 organs were provided by 11,074 donors in the first six months of 2019.\(^4\) Approximately 70

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\(^2\) Ibid.


percent of those remaining on the waitlist will not receive the transplants they need in 2019,\(^5\) and approximately 33 people die every day while waiting for a critical transplant or are removed from the waiting list after being deemed too sick to receive a transplant.\(^6\)

Many of these deaths are unnecessary and caused by underperformance in the organ procurement industry. As a country, we have an ability to recover nearly 28,000 more organs from deceased donors annually, which would save thousands of lives and “billions in taxpayer funds from the avoided costs of dialysis and increased productivity.”\(^7\) Yet industry statistics suggest that OPOs have lost nearly 25 percent of their most promising cases, approximately 3,000 donors a year, due to issues regarding consent.\(^8\)

OPOs are at the heart of this problem. 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. UNOS “serves as the OPTN under contract with the Health Resources and Services Administration (HRSA),”\(^9\) a division of HHS.\(^9\) OPOs are 100 percent reimbursed for all costs via Standard Acquisition Charges (SACs). Each OPO can establish its own SAC for each type of non-renal organ it evaluates and procures. The SAC is then paid to the OPO by the transplanting hospital for each organ it receives. Little is standardized in this process, and much is left up to OPOs, including methodologies for determining their individual SACs.\(^10\)

Nationally, there are 58 OPOs, each “operating as an unchecked regional monopoly,”\(^11\) 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.”\(^12\) This central concern is what I request you address in any forthcoming regulations in response to the President’s efforts to improve our organ transplant system.

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\(^9\) *Organ Procurement and Transplantation Network.* US Department of Health and Human Services, optn.transplant.hrsa.gov/governance/about-the-optn/.


Other than a recent increase in donation rates owing to the opioid epidemic\textsuperscript{13}, the majority of persistent underperformers have not improved their rates over the last decade.\textsuperscript{14} Performance is measured by the number of donors from whom the OPOs recover organs compared with the total potential pool of donors from whom the OPOs could have recovered organs. Every American can and should decide for themselves whether organ donation is right for them. However, 95\% of Americans already support organ donation, and it is incredibly troubling that so often OPOs fail to honor those wishes.\textsuperscript{15} OPOs are the only organizations that can recover organs from deceased donors for transplantation, placing an enormous responsibility on these organizations to serve patients in need.\textsuperscript{16} This lifesaving work is only possible if OPOs function appropriately.

Under federal regulations, in addition to the control OPOs have over their SACs, OPOs operate within an evaluation system that does not reward pursuing every organ that becomes available for transplant and which allows for self-reporting that can make determining success impossible. For example, the federal contract for managing organ donations that has been held by the same organization for three decades is worth nearly $58 million a year, but “[b]ecause most of that money comes from patient fees, there is more of an incentive to add patients to the wait list than to secure organs for them.”\textsuperscript{17} Additionally, current performance metrics emphasize the one-year survival rate of their transplant patients “but not by the number of patients who die while waiting for a transplant to come through,” which creates a powerful incentive . . . to reject organs from older or slightly sicker donors, even when those organs could be lifesaving.\textsuperscript{18} In simpler terms, the incentive favors rejecting organs with a higher risk of failure, even if they would save lives, while benefitting from allowing the waitlist to grow.

Self-Reporting OPO Data

Federal law requires CMS to conduct necessary oversight over OPOs, and in turn CMS requires OPOs to submit annual Medicare cost reports “to determine the amounts payable under Medicare associated with the procurement of kidneys.”\textsuperscript{19} The reports include direct costs, overhead costs, and administrative and general costs associated with organ procurement.\textsuperscript{20} CMS has the authority


\textsuperscript{16}About OPOs. Association of Organ Procurement Organizations, www.aopo.org/about-opo/.


\textsuperscript{18}Ibid.


\textsuperscript{20}Ibid.
to decertify underperforming OPOs, but in 20 years not a single OPO has ever been decertified, despite evidence of widespread mismanagement and underperformance.\textsuperscript{21,22,23}

According to CMS, “[t]he costs claimed in the cost report must be related to the care of beneficiaries; reasonable, necessary, and proper; and allowable under Medicare regulations (42 CFR § 413.9(a), (b), and (c)(3)).”\textsuperscript{24} These flexible, non-uniform standards for cost reporting and other OPO performance metrics allow OPOs to report that their procurement rates are significantly higher than they are in reality.

The vast majority of OPOs significantly exaggerate their organ procurement rates, while research has found that their recovery rates are significantly lower.\textsuperscript{25} This has led prominent healthcare analysts and scientists, such as DJ Patil, the former Chief Data Scientist at the White House Office of Science and Technology Policy of the United States, to refer to current data for OPOs as “functionally useless.”\textsuperscript{26} Even the Association of Organ Procurement Organizations, a trade group representing OPOs, claimed that “self-reported” data could not be used for decertification because “accuracy and consistency of data cannot be assured.”\textsuperscript{27}

In 2012, CMS identified LiveOnNY, the OPO serving New York, as recommended for decertification based on its performance. Unfortunately, LiveOnNY is still in operation and was allowed to continue its contract with CMS on the basis that its own performance metrics were so inadequate as to invalidate CMS’s attempt to decertify. They wrote: “[Our data is] ‘self-reported


and unaudited...[so] 'clearly... fails to meet any reasonable definition of empirical,'" essentially claiming that because their data was so inaccurate that it could not be used as a valid metric to prevent them from further operation. Six years later, the LiveOnNY has continued to underperform and, as a result, nearly 6,000 New Yorkers have either died or been removed from the waiting list after becoming too sick to receive transplants in the absence of any meaningful governmental action against the OPO. The OPO was never decertified, and there are no apparent updated metrics available on their website.

Los Angeles OPO Financial Mismanagement and Performance

My constituents in California’s 45th Congressional District are serviced by an OPO based in Los Angeles – OneLegacy. OneLegacy serves 20 million Californians in Los Angeles County and the surrounding area, including Orange, Ventura, Riverside, Santa Barbara, Kern, and San Bernardino counties. OneLegacy has 5 offices, serves 215 hospitals, including 11 transfer centers.

California has the longest transplant waiting list in the country at nearly 22,000 people. While this is partially based on the size of California’s population, no other state has a waiting list of more than 10,500. According to research supported by Arnold Ventures, which completed a detailed analysis of organ procurements from 2012 to 2014, OneLegacy reported to CMS that it recovered 69 percent of potential organ donors. In reality, OneLegacy actually only recovered 31 percent of potential organ donors, making it one of the worst performing OPOs in the country. This discrepancy is largely the result of self-reporting of data.

More recently, using the metric that CMS proposed in its RFI released after the President’s Executive Order, which is the number of donors per 1,000 inpatient deaths age 75 and younger with cause of death consistent with organ donation, OneLegacy recovered only 93.7 donors per thousand deaths in 2017. By comparison, the OPO serving San Diego and its surrounding area recovered 154.5 per thousand. Despite having similar patient demographics and challenges, the San Diego OPO recovered 65 percent more donors.

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29 Ibid.
36 Ibid.
While failing to help the lives of patients it is federally designated to serve, OneLegacy spent more than $500,000 on “unallowable or poorly documented items,” according to a federal audit conducted in 2010 by the HHS Office of the Inspector General (OIG).37 The audit of OneLegacy’s Medicare cost report found that OneLegacy “did not fully comply with Medicare requirements for reporting selected OPO overhead costs and administrative and general costs in its FY 2006 Medicare cost report.”38 There were a total of $531,460 in unallowable and unsupported costs.39 Of those, $290,968 were costs unrelated to patient care.40

The audit found that OneLegacy had spent $327,000 on the Rose Bowl game and parade, “including float design and framework, football tickets, hotel rooms, limousines and flowers.”41 Of that, $150,000 was improper, auditors said in a 2010 report, leading to a Medicare overpayment of $85,000. OneLegacy has continued to spend money on the Rose Bowl and submit a portion of its $75,000 per year float-sponsorship expenses to Medicare. In 2013, the CEO, Thomas Mone, claimed that these costs were necessary and appropriate because they generated enough media attention to balance these costs.

Following the audit, rather than take steps to boost its clinical performance or strengthen its financial management and controls, OneLegacy established a foundation in order to use private donations to pay for the majority of the costs related to the Rose Bowl.42 According to the foundation’s most recently available tax filings, the foundation received $20-30 million in OPC funds in 2016.43 This money, rather than going to patients in need, now funds many of the same expenses that the OIG deemed impermissible, such as costs related to the Rose Bowl.

OneLegacy also funds exorbitant salaries for senior leadership, rather than focusing solely on the needs of the thousands on California’s organ transplant waiting list. Investigative reporting has found that OneLegacy pays its board members extravagantly. OneLegacy paid Dr. Robert Mendez, President and Chairman of the OPO, $109,209 in 2011, even though “he averaged 10 hours a week” of work.44 Similarly, his brother, Dr. Rafael Mendez, who co-founded OneLegacy with him in 1977, received $33,271 for an average of two hours of work per week as his brother’s secretary.45 Thomas Mone, who has served as the CEO of OneLegacy for nearly 20

38 Ibid.
39 Unsupported costs are those that had no documentation existing to explain the reported costs.
40 Ibid.
42 Ibid.
45 Ibid.
years through the OIG investigation was paid a total compensation of nearly $1 million annually. OIG has not conducted or pursued a decertification of OneLegacy. These exorbitant salaries are funds, many which have come from taxpayers, that could have instead gone to the recovery of lifesaving organs.

OneLegacy is not the only OPO in California, or across the country, mismanaging funding. According to federal auditors, the California Transplant Donor Network, which serves Oakland, California and surrounding areas, spent more than $167,000 that was either “improper or poorly documented as taxpayers’ expenses.” In 2007, California Transplant Donor Network hosted a retirement party for then CEO Phyllis Weber. The party cost nearly $20,000 and $9,600 was inappropriately paid for by taxpayers. Additionally, the nonprofit spent $12,000 on banquet expenses for a staff meeting and $10,500 to sponsor a minor league baseball team. The organization did not face any repercussions when federal auditors discovered the impermissible spending. CMS has not taken any actions against the OPO to date. Given that OPOs have been found to miss potential organ recoveries because they are “short-staffed at critical moments, causing transplant coordinators to show up late or not at all to speak with grieving families,” it is particularly disturbing that taxpayer resources are used on items which do not increase organ donations.

Questions

Senator Elizabeth Warren and Senator Richard Blumenthal sent a letter on July 8, 2019 regarding OPO performance and requested a staff level briefing. We appreciate your willingness to move this issue forward. I request that you also answer the following questions no later than October 28, 2019 regarding your agencies’ efforts to address OPO underperformance and financial mismanagement, as well as your plan to address these issues in the context of President Trump’s Executive Order, which calls for a new metric that is “transparent, reliable, and enforceable” within 90 days.

1. Why have no OPOs been decertified in decades – despite chronic underperformance and documented fraud, waste, and abuse of taxpayer funds? Has OIG conducted any additional audits of previously investigated OPOs, like OneLegacy, and if not, have any

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47 Tigas, Mike, et al. OneLegacy Foundation - Nonprofit Explorer. ProPublica, projects.propublica.org/nonprofits/organizations/452936915
49 Ibid.
50 Ibid.
other steps been taken to conduct necessary oversight over OPOs that have acted similarly?

2. Given the ultimate oversight authority lies with CMS, how – if at all – has engaging an additional government contractor (the OPTN) led to system accountability in the patient interest? If it has, where can patients go for transparency to see how and where the OPTN has held failing OPOs accountable?

3. The Executive Order directs HHS to “to establish more transparent, reliable, and enforceable objective metrics for evaluating an OPO’s performance” – how quickly can HHS move to institute such metrics and decertify failing OPOs?

4. Since OneLegacy created its foundation in conjunction with the organization’s nonprofit operations, various other OPOs across the country have established similar financial structures. What, if any, oversight has CMS conducted over the relationship between funding being passed between the arms of these organizations?

   a. Would CMS consider establishing guidelines for foundation management and donations in order to ensure this creates no conflicts of interest?

5. Given that OPOs are 100 percent reimbursed for all costs via Standard Acquisition Charges (SACs), what is being done at a Federal level to curb the incidence of fraud, waste and abuse and to ensure that taxpayer funds are well spent in patient interests?

We owe it to the more than 110,000 patients who remain on the organ transplant waitlist to address this issue as quickly as possible. Every month, 1,000 patients are “removed” from the organ waiting list because they have died or become too sick to transplant. HHS and CMS should try to save these lives through meaningful oversight. I look forward to receiving your response prior to October 28th. Please do not hesitate to reach out to my office with any questions you may have.

Sincerely,

[Signature]

Representative Katie Porter