30 October 2019

The Honorable Alex Azar
Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave S.W.
Washington, D.C. 20201

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
200 Independence Ave S.W.
Washington, D.C. 20201

Dear Secretary Azar and Administrator Verma,

Thank you for your crucial and timely leadership on OPO reform. As a transplant recipient and President & CEO of the Global Liver Institute, this issue is important to every family who has or has had a loved one waiting for a life-saving organ transplant, each family who has made the generous decision at the lowest point in their lives to donate, and to all taxpayers who depend on government oversight and stewardship of public dollars to improve the nation's health.

I have worked in the transplant field since my own transplant 25 years ago in various capacities, including on staff as a patient affairs specialist at UNOS and later serving on the UNOS Membership & Professional Standards Committee, and so fully understand the context and history of the issues involved in OPO performance metrics and efforts to bring about accountability. I understand the power of informed, data-driven policy to create a workable solution. As such, I would like to bring to your attention a highly misleading Media Fact Sheet released by the Association of Organ Procurement Organizations (AOPO) that tries to call into question remarks made by President Trump when he signed the Executive Order.

Given the importance of the Executive Order, and your leadership in implementing it, I feel it is important to correct the record in the interest of informing patient-centric policy using the best available information.

I understand that Bryan Sivak, former Chief Technology Officer of the Department of Health and Human Services, wrote to you in August for similar reasons. It is troubling that government contractors would release misleading information calling into question the Administration's previous statements, though please know that the Global Liver Institute stands with you in efforts to move forward in ways that bring truth and integrity to reforming the organ donation system and help more patients access life-saving transplants.

Sincerely,

Donna R. Cryer, JD
President & CEO
Global Liver Institute
dcryer@globalliver.org

AOPO claim: The claim that 28,000 organs are 'missed' and go unrecovered each year is false. The number comes from a non-peer-reviewed report developed for lobbying purposes in which the authors acknowledge their numbers are inflated (pg. 6). They note their estimates represent the "full potential of the system, assuming 100-percent donation rates and 100-percent organ utilization."

Fact check: The 28,000 organs number that was cited by President Trump during remarks for the Executive Order comes from research led by Dr. David Goldberg, then of the University of Pennsylvania, which built upon previous research, including a UNOS-led, HRSA-sponsored study. In fact, Dr. Goldberg's estimate is based on a full donor potential of nearly 24,000 donors annually, which is a more conservative estimate than the UNOS-led research, which estimated a potential donor pool of 38,000 donors every year.

Dr. Goldberg's research and methodology were subsequently published as a peer-reviewed study in the *American Journal of Transplantation*, with co-authors including two other physicians (including a former Surgeon General) and two OPO executives. Only after that publication did the Bridgespan Group publish policy recommendations building upon Dr. Goldberg's peer-reviewed research. AOPO's claim that Bridgespan's paper is not peer-reviewed is incredibly misleading, as the research it cites, led by Dr. Goldberg, was, in fact, peer-reviewed.

Additionally, the quotation AOPO cites on page 6 of the Bridgespan report in no way acknowledges that the numbers are inflated. The direct quote is: *"It is important to note that the above figures represent the "full potential" of the system, assuming 100-percent*

donation rates and 100-percent organ utilization. Achieving even 20-percent of this potential improvement would result in approximately 6,000 lives saved per year and $2.6 billion in taxpayer savings over five years."

This is meant to provide a scale for how impactful reforms could be even if OPOs never realize their full potential; it does not imply that the research to inform that full potential is inflated.

AOPO claim: Less than 1 percent of all people die in a way that allows for organ donation.

Fact check: Dr. Goldberg's peer-reviewed research found a donor potential of nearly 24,000 donors per year, which represents 3.3% of all in-hospital deaths.

AOPO claim: Organ procurement organizations (OPOs) aggressively pursue donation possibilities ... and for any death that might have donor potential, OPOs send staff onsite to perform detailed medical record reviews of patient data to assess medical suitability and ensure potential organ donors are not missed. OPOs have absolutely no incentive to do anything but the best job possible and recover as many organs as possible. OPOs are only reimbursed when they succeed at their mission.

Fact check: OPOs vary in practice and performance, just as hospitals and transplant centers vary. What distinguishes OPOs is that we don't have an objective way to evaluate their performance or, by extension, to quantify that variability. According to recent reporting from the *Associated Press*, "some [OPOs] are securing deceased donors at half the rate of others — even as 113,000 people linger on the nation's transplant waiting list."

An OPO whistleblower also recently told the *New York Times* that OPOs do not pursue all potential donation cases, and the *Washington Post* reported on the New York City OPO being "short-staffed at critical moments" and that "interviews and records show that transplant coordinators have shown up late or not at all to speak with grieving families."

Historically, these behaviors have been masked by what the OPO whistleblower told the *New York Times* is a "culture of dishonesty" at OPOs and what the *New York Times* Editorial Board subsequently characterized as "astounding lack of accountability and oversight in the nation's creaking, monopolistic organ transplant system [that] is allowing hundreds of thousands of potential organ donations to fall through the cracks."

Also, while OPOs may only be reimbursed when they facilitate an organ donation, that is not to say they are financially incentivized to maximize donation. Because OPOs are, as described by the *New York Times* Editorial Board, "monopolistic," they are able to monopolistically set the prices at which they sell the organs they recover to transplant centers; if an OPO recovers fewer organs than they expect in any given year, they can simply increase their prices to offset the drop in volume.

Investigative reporting has found an OPO culture rife with fraud, waste and abuse, including misspending taxpayer resources on private planes, retreats at 5-star hotels, lavish office parties, golf tournaments, and football tickets, which has been substantiated by audits by the Inspector General. OPO management salaries can exceed $2.5 million annually, and investigative reporting has also highlighted OPO practices of "nepotism" and "board members paying themselves," all in an industry which peer-reviewed research has found to be grossly underperforming.

Finally, AOPO's own claim that OPOs "have no incentive to do anything but… recover as many organs as possible" is belied by their own above-cited 2013 letter to the White House Office of Management and Budget in which they admit to "gaming the [CMS metrics] by only targeting "high-yield" organ candidates [i.e. choosing not to recover from donors with only one or two organs available for donation, even if that person had been a registered organ donor]."

AOPO claim: The number of organ donors and lifesaving organ transplants continues to grow. The nation saw its eighth straight record year for organ donation in 2018. And, based on data through the first nine months of this year, 2019 is on track to see a 9 percent increase in deceased organ donors over 2018. At the current pace, AOPO projects 2019 could see an additional 1,000 donors and 3,000 organs transplanted over last year.

Fact check: As has been pointed out in previous fact-checking of misleading AOPO claims, while this is technically true, it is also enormously misleading; according to researchers at UNOS, Brigham and Women's Hospital, Eurotransplant International Foundation, and University of Utah Health, the recent increase in donations, and therefore transplants, are due to the opioid epidemic rather than improvements in OPO performance. According to Mandeep R. Mehra, MD, medical director of the Heart and Vascular Center at Brigham and Women's Hospital and first author on the study: "We were surprised to learn that almost all of the increased transplant activity in the United States within the last five years is a result of the drug overdose crisis."

AOPO claim: Opioid overdose deaths are not driving the increase in organ donors. Drug intoxication deaths, which includes opioid and others, have accounted for only about one-third of the growth in organ donors nationally since 2012. Since 2016, the number of drug intoxication donors has remained relatively flat at just 12-13% of total donors – a trend that is continuing into 2019. The increased use of organs from donors who have died from overdose illustrates both that OPOs are successful in their responsibilities of actualizing potential donors, and an important shift in perceptions among transplant professionals and the public about the acceptability of such organs.

Fact check: The data AOPO cites are not peer-reviewed and come from their own Fact Sheet using self-reported information from OPOs. OPOs also have tremendous discretion in the process of coding the mechanism of death for each donor, with no specific guidance from the OPTN, and the data are not audited or validated by external review.

For example, a donor resulting from an opioid overdose can alternatively be coded as having "asphyxiation" as the mechanism of death, leading to highly misleading, OPO-reported statistics about the impact of the opioid epidemic on the recent increase in donation rates.

AOPO claim: Organ, eye and tissue donation does not compromise death investigations.
The National Association of Medical Examiners supports donation and concluded in its 2014 position paper, Medical Examiner Release of Organs and Tissues for Transplantation, that with proper communication and cooperation the medical examiner and coroner can allow for procurement of at least some, if not all, organs and/or tissues and fulfill their legal mandates without detriment to death investigations.

Fact check: The *Los Angeles Times* recently published an investigation detailing how OPOs have used their substantial financial resources to curry influence with the National Association of Medical Examiners, and described the 2014 position paper AOPO cites as a "flawed paper [which] gave industry cover." The *Times* specifically notes: "what is rarely if ever mentioned is that two of the paper's seven authors work as top executives at procurement companies and two others are medical examiners who serve on a company's advisory committee."

Additionally, what is at issue is not whether it is *possible* that procurement can proceed without compromising death investigations, but rather whether the practice of procurement sometimes *does compromise* deaths investigations. According to this investigative series, "*Times* reporters also found more than two dozen other cases in two Southern California morgues where procurement appeared to hamper death investigations." That it is possible to procure without compromising investigations — coupled with historical records to indicate that procurement, in practice, does compromise investigations — would suggest lapses in quality control.

Of note: the *Times* also reported that "[OPO] Executives coached coroners on how to keep body parts harvesting records secret" in efforts to obstruct their investigation.

AOPO claim: The system for organ, eye and tissue donation in the United States is highly regulated. Federal agencies with oversight of organ or tissue donation include the U.S. Department of Health and Human Services (HHS) and its branches, the Centers for Medicare & Medicaid Services (CMS), the Food and Drug Administration (FDA) and the Centers for Disease Control (CDC). Additionally, each state has its own requirements for organizations that perform organ and tissue recovery and OPOs must follow Organ Procurement & Transplantation Network (OPTN) policies and bylaws. Further, there are industry-specific accreditation requirements.

Fact check: As has been pointed out in previous fact-checking of misleading AOPO materials, while AOPO lists the various bodies who have some form of oversight over OPOs, what is at issue is how effective this regulation is in practice.

As noted above, the *New York Times* Editorial Board characterized as suffering from "an astounding lack of accountability and oversight," and a 2013 letter from AOPO to the Office of Management and Budget argued: "[OPO] data are unaudited and self-reported, [and] there is no provision for even random audits of the data submitted by OPOs to assess the accuracy of the data reporting."

It is also worth noting the role of the OPTN. With regard to OPO performance related to organ recovery, the OPTN is tasked by the Final Rule 1221.10 to "design appropriate plans and procedures… a peer review process, and data systems, for the purpose of… conducting ongoing and periodic reviews and evaluations of each member OPO... for compliance with these rules and OPTN policies."

Despite this language, the OPTN exerts minimal oversight of OPOs, and has been characterized in media reporting as a "reluctant enforcer" with "collegiality...built into [its] very structure." As a consequence, OPO underperformance continues unaddressed and unremediated for extended periods of time while the waiting list patients in those areas are left to suffer.

Regardless of any OPTN role, the ultimate responsibility for ensuring OPO accountability rests with CMS. As was noted in a recent *Washington Post* report about UNOS's failure to provide meaningful oversight over the Miami OPO after it failed to report a near-fatal infection in a uterus it recovered for transplant, "safety standards are enforced by UNOS, [but]... only the federal Centers for Medicare and Medicaid Services (CMS) can shut down an organ procurement group." Forbes has gone as far as to characterize UNOS as "a cartel" and the "federal monopoly that's chilling the supply of transplantable organs and letting Americans who need them die needlessly."

In practice, there is no effective oversight of OPO performance. As Senator Todd Young has noted, "[the OPTN] has operated in the darkness for decades." Similarly, Senator Grassley has described the OPTN as "kind of like the fox guarding the chicken house."

AOPO claim: OPOs support the development of a new independent donation rate performance metric that can be used to drive improvements in their ability to recover and deliver organs to those who need them. In comments to the Centers for Medicare & Medicaid Services (CMS), AOPO noted that the current rulemaking process is an exceptional opportunity to drive meaningful change and increase the availability of organs for transplantation.

Fact check: AOPO's comment to CMS does not actually support the implementation of new metrics, but rather "further exploration" of data sources to inform a new metric. Of note: there have been Government Accountability Office reports studying OPO metrics dating back to 1998. Also, while other groups, including the Global Liver Institute, have

been actively advocating for new OPO metrics for years, AOPO only first took its current position *after* the President's recent Executive Order directing the HHS Secretary to propose new OPO metrics.

AOPO claim: If you are writing about organ donation, we hope you will include the facts below and reach out to our organizations for additional information or to speak to experts.

Fact check: AOPO suggests that reporters should reach out to them before writing about organ donation, and OPO CEOs have previously actively invited reporters to visit their local OPOs. If a reporter — as well as any Federal oversight bodies — are planning to do so, below are additional questions which would be useful to ask:

- Please provide an itemized list of all costs that are used to calculate the standard acquisition costs you set for organs.
- Please also disclose the 2018 full compensation for your CEO — including base salary, bonuses, and compensation from other organizations, including for-profit organizations with which the OPO partners.
- Please provide de-identified data on all donor referrals made by all of your partner donor hospitals so there can be an accurate determination of your donor potential.
- Has your OPO ever been placed on a corrective action plan or deemed by UNOS to be a "member not in good standing? If so, why? And, if you have been subsequently restored to "member in good standing," please provide documentation regarding the process by which that happened.
- Please list your OPOs tissue partners (whether it is all handled within the organization or if there are external partners as well), which parts of the tissue business (your own, or your partners) are for profit, and how this relationship is communicated to potential donor families.
- What percentage of tissue you recover is used for cosmetic purposes?
- How much money has been transferred from your OPO to any morgue or coroner's office? For any moneys transferred, please provide justification.

There is a tremendous need for organs for transplant. More than 113,000 people are currently on the transplant waiting list in the United States and the donation and transplantation community works every day to help save and improve their lives. ***There is currently a significant amount of misinformation being spread about the process for deceased organ donation***, and particularly, that the supply problem is easily solvable because 'thousands of transplantable organs go unrecovered each year.'

Narrowing the gap between available organs and those in need of a lifesaving transplant is a complex problem that deserves attention. However, misinformation discourages donation and fosters mistrust in what is a highly regulated and successful system. Misinformation harms the goal of saving more lives.

If you are writing about organ donation, we hope you will include the facts below and reach out to our organizations for additional information or to speak to experts.

The claim that 28,000 organs are 'missed' and go unrecovered each year is false.
The number comes from a non-peer-reviewed report developed for lobbying purposes in which the authors acknowledge their numbers are inflated (pg. 6). They note their estimates represent the "full potential of the system, assuming 100-percent donation rates and 100-percent organ utilization." They do not take into account the many clinical factors, and transplant program preferences and acceptance practices, that limit organ donation in a real-world setting.

Organ donation is truly a rare event.
Less than 1 percent of all people die in a way that allows for organ donation. Organ donors have to meet extensive criteria, including dying in a hospital and on a ventilator, passing a host of medical tests, such as being free of most cancers and organ damage, having their organs accepted by the transplant teams, and most importantly, there must be authorization for donation.

Organ procurement organizations (OPOs) aggressively pursue donation possibilities.
OPOs will screen more than 700,000 telephone death referrals from hospitals for the potential of organ donation this year alone. And, for any death that might have donor potential, OPOs send staff onsite to perform detailed medical record reviews of patient data to assess medical suitability and ensure potential organ donors are not missed.

OPOs have absolutely no incentive to do anything but the best job possible and recover as many organs as possible. OPOs are only reimbursed when they succeed at their mission – assisting donor families in carrying out their decisions to save lives through organ donation and delivering organs to transplant programs for their patients on the transplant waiting list.

By law, OPOs are the only organizations that can perform the lifesaving mission of recovering organs from deceased donors for transplantation.
The 1984 National Organ Transplant Act established today's system of organ donation and recovery to standardize the process for donation and ensure fair and equitable allocation of donated organs. The 58 federally designated and regulated OPOs represent a community of professionals across the country dedicated to saving and healing lives. Their commitment is evident 24-hours-a-day, 365 days a year in their care and compassion for organ donors and their families.

The number of organ donors and lifesaving organ transplants continues to grow.
The nation saw its eighth straight record year for organ donation in 2018. And, based on data through the first nine months of this year, 2019 is on track to see a 9 percent increase in deceased organ donors over 2018. At the current pace, AOPO projects 2019 could see an additional 1,000 donors and 3,000 organs transplanted over last year.

October 25, 2019

Opioid overdose deaths are not driving the increase in organ donors.
Drug intoxication deaths, which includes opioid and others, have accounted for only about one-third of the growth in organ donors nationally since 2012. Since 2016, the number of drug intoxication donors has remained relatively flat at just 12-13% of total donors – a trend that is continuing into 2019. The increased use of organs from donors who have died from overdose illustrates both that OPOs are successful in their responsibilities of actualizing potential donors, and an important shift in perceptions among transplant professionals and the public about the acceptability of such organs.

Organ, eye and tissue donation does not compromise death investigations.
The National Association of Medical Examiners supports donation and concluded in its 2014 position paper, *Medical Examiner Release of Organs and Tissues for Transplantation*, that with proper communication and cooperation the medical examiner and coroner can allow for procurement of at least some, if not all, organs and/or tissues and fulfill their legal mandates without detriment to death investigations.

The system for organ, eye and tissue donation in the United States is highly regulated.
Federal agencies with oversight of organ or tissue donation include the U.S. Department of Health and Human Services (HHS) and its branches, the Centers for Medicare & Medicaid Services (CMS), the Food and Drug Administration (FDA) and the Centers for Disease Control (CDC). Additionally, each state has its own requirements for organizations that perform organ and tissue recovery and OPOs must follow Organ Procurement & Transplantation Network (OPTN) policies and bylaws. Further, there are industry-specific accreditation requirements.

OPOs support the development of a new independent donation rate performance metric that can be used to drive improvements in their ability to recover and deliver organs to those who need them.
In comments to the Centers for Medicare & Medicaid Services (CMS), AOPO noted that the current rulemaking process is an exceptional opportunity to drive meaningful change and increase the availability of organs for transplantation. OPOs are persistent and committed in their quest for improvement. Adoption of an improved metric, based on data that is independently reported, collected consistently across the country, available in a timely manner and sufficiently granular to calculate reasonable risk adjusted organ donation potential, that is not in conflict with transplant performance metrics, will better enable OPOs to identify additional opportunities for improvement.

Everyone shares the goal of reaching the day when no one dies while on the transplant waiting list.
This a complex problem and its solutions extend beyond organ procurement to include all aspects and all stakeholders involved in donation and transplantation. This includes donor hospitals, transplant programs, insurance companies, government partners and medical and technological advancements that are yet to be developed. A series of comprehensive systems improvement solutions are necessary. Measures that can make a difference today include:

1. **Removing regulatory disincentives** that keep transplant centers from using organs from donors that are older and medically complex. Studies have shown that many organs, while medically complex, are still medically viable and offer transplant patients the chance for a better quality of life.
2. **Improving hospital clinical support for organ donors** and promoting the use of organ recovery centers.
3. **Ensuring OPO access to donor hospital electronic health records**.
4. **Continued support to educate all communities to register to be a donor on the national registry, Registerme.org.** A single deceased organ donor, who dies in a way that allows for donation and meets the necessary criteria, can save up to eight lives and improve the lives of many others through eye and tissue donation. The more people who are registered, the more likely it is that more lives can be saved and healed.

For more information, please contact:

AOPO
media@aopo.org

Donate Life America
Hilary Czarda
hczarda@donatelife.net