aopo
association of
organ procurement organizations®

Legislative or Regulatory Perspective
AOPO Recommendations
to
Support and Increase Donation and Transplantation

1. **Increase Organ Donation and Transplantation from the pool of donor potential identified as the biggest opportunity for growth – older, DCD and more complex donors** by removing financial disincentives and promoting utilization of organs from these donors. Every recently published study of the organ donor potential in the U.S. has consistently identified older donors (over 60) and donors after circulatory death (DCD) as the two most significant opportunities for growth. Capturing this donor "potential" requires system-wide strategies focused on increasing the transplantation of organs from donors in these categories and organs from more medically complex donors. These potential donors are already being identified by OPOs under the current system, but the organs are not being used as evidenced by higher organ discard rates and lower yield performance for older, more medically complex and DCD organ donors. Utilization of organs from these donors is significantly lower in part because (a) although expected outcomes from being transplanted with these organs are beneficial to patients as compared to expected outcomes if they do not receive an organ transplant, the transplant center performance metrics are not adequately risk-adjusted creating a regulatory disincentive to utilize these organs and (b) more complicated post-transplant care required for recipients of these organs is not adequately reimbursed. See attached articles by Axelrod 2017, Axelrod 2018, and Cooper 2019. These are regulatory disincentives that can be removed by adjusting the CMS performance metrics (regulation) and the DRGs for transplant centers (payment). These two changes could over time significantly accelerate growth in transplantation by utilizing organs from a group of potential donors estimated to be somewhere between 1.5 and 2 times the currently defined medically suitable pool of organ donors.

    a. **Remove regulatory disincentives** by directing CMS to adopt a risk adjustment model that more accurately measures transplant outcome performance, taking into account donor risk factors that are medically complex (e.g., DCD, PHS increased risk donor), recipient risk factors and comorbidities, donor and recipient age, long term survival rates with a comparative to waitlist mortality. 42 C.F.R. 482.80(c); § 482.82(c) (https://www.govinfo.gov/content/pkg/CFR-2011-title42-vol5/pdf/CFR-2011-title42-vol5-sec482-82.pdf)

    b. **Remove financial disincentives** by adjusting DRGs to increase payments for recipients of organs from complex donors to account for more costly post- transplant care. DRGs are set annually by CMS. 42 CFR § 412.60 - DRG classification and weighting factors. https://www.govinfo.gov/content/pkg/CFR-2018-title42-vol2/pdf/CFR-2018-title42-vol2.pdf (at p. 600). This would not be a regulatory change, but a payment policy change.

2. **Increase Organ Donation by better clinical support of potential donors at the hospital and recoveries at the OPO -** by providing hospital incentives to foster cooperation with OPOs in caring for donors and their families, preserving and maintaining the option for donation for all potential donor candidates and providing the services needed for OPOs to ensure successful donation. For example, currently with "do not resuscitate" (DNR) orders, care of patients can rapidly diminish which can result

in otherwise suitable organs becoming no longer suitable for transplantation, before there is an opportunity to evaluate and determine donation potential and seeking authorization for donation.

Additionally, remove financial disincentives for centralized OPO surgical recovery centers. The surgical recovery of organs from deceased donors through centralized OPO surgical recovery centers can significantly improve operational and cost efficiencies in the system. This improvement would reduce the time delays, variable costs and complex logistical coordination currently required to schedule OR times within donor hospitals without disrupting scheduled and unscheduled surgical needs of the hospital's living patients while maximizing transplant outcomes dependent on time-critical recovery of organs from deceased donors. One of the barriers to wide-spread implementation is a CMS policy that creates a significant financial disincentive to moving organ donors for surgical recovery from hospitals that are transplant centers (which is where the majority of potential donors are identified because these hospitals are also often major trauma centers). Changing this policy would facilitate value-driven system-wide improvement. This operational strategy is particularly important as the system moves to broader sharing of organs under OPTN distribution policies.

3. **Improve OPO Performance Evaluation through independent collection and reporting of data to build an OPO metric** by requiring all hospitals through EHR meaningful use provisions to report deaths of all in-patients that are ever placed on a ventilator to the OPTN/SRTR. This will assist in providing data that could be used to develop meaningful measures that will more accurately determine medically suitable donation potential on a nation-wide scale and allow for better OPO performance evaluation.

4. **Increase Organ Donation by ensuring efficient access to potential donor information** by requiring seamless access to donor hospital EHRs. OPOs require access, both on-site as well as remotely, to hospital EHRs to perform the functions of donation and transplantation. OPOs need to read, write, modify and communicate information in those records, including communication to persons outside the hospital EHR system. The OPO needs to enter information in the hospital EHR, and may need to print, download, and share information such as blood work, test results, x-rays and scans. The OPO is required by law to include in its own donor record information that is created in, or derived from, the hospital EHR, and to provide this information for donor recipient matching purposes. In general, hospital EHR systems have not been designed to permit OPOs to perform these basic functions.

   HIPAA Regulations expressly authorize hospitals to "use or disclose protected health information to organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of cadaveric organs, eyes, or tissue for the purpose of facilitating organ, eye or tissue donation and transplantation." 45 CFR 164.512(h) (referred as "§164.512(h)") HIPAA Regulations, thus, are not an impediment to hospitals fulfilling their obligations to OPOs.

   OPOs across the country are finding it very difficult to obtain the fast, easy, assured access they require. The ability of OPOs to perform their responsibilities is being adversely impacted by the manner in which these EHR systems are being implemented. The systems have been designed and implemented without taking account of the needs and obligations of OPOs. To a greater or lesser extent, the problem affects all OPOs, all hospitals, and the products of all EMR/EHR vendors. Hospitals should be legally mandated to provide all OPOs with EMR/EHR access needed to fulfill the OPOs statutory responsibilities, without undue burden placed upon the OPO.