

# OUR PRACTICE

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## Organ Donation and Transplant

Each year, donated organs save thousands of lives, but the need is much greater. Hospital providers, organ procurement organizations (OPOs), transplant hospitals, and related donation and transplant entities face complex legal requirements and a constantly evolving policy landscape. Our team is dedicated to helping them navigate these challenges so they can focus on their life-saving work.

We recognize the vital role hospitals, OPOs, tissue processors, donor registries, and transplant centers play in the donation and transplantation system, and understand the stringent governmental oversight they face. Our experience in this area spans all levels of compliance with state and federal laws and regulations, including those governing organ recovery procedures, authorization for donation, transportation needs, donor-family interface, staff training, transplant center relationships, data management and reporting, and health-equity concerns.

We provide guidance on First Person Authorization and the Uniform Anatomical Gift Act and help ensure compliance with relevant regulations, organ allocation policies, and data privacy mandates. We assist in formulating procedures and policies related to training, ethics, documentation, and recordkeeping in order to help mitigate legal risks and reduce potential liabilities.

With extensive experience advising OPOs, transplant centers, and affiliated entities across the country, we offer holistic, firm-wide legal services to address a multitude of needs, from navigating Congressional and other government inquiries and investigations to analyzing new rules proposed by federal oversight agencies and the Organ Procurement and Transplantation Network (OPTN) to corporate governance restructuring and expansion through mergers and acquisitions. We also provide guidance on legislative and policy initiatives that alter dynamics in and between OPOs, transplant centers, donor registries, and federal oversight entities.

Our comprehensive services encompass:

- **Legal and Regulatory Compliance:** Ensuring compliance with relevant federal and state laws and regulations, including CMS performance-based regulations, the UAGA, the Uniform Determination of Death Act (UDDA), and the National Organ Transplant Act (NOTA);
- **Policy Guidance:** Providing insights and strategy regarding the impact of proposed industry rules and regulations and drafting comments in response to the same;
- **Government Inquiries:** Managing responses to inquiries and investigations from relevant government agencies and oversight entities, including HHS, CMS, HRSA, FDA, OPTN, and AATB;
- **OPO Mergers:** Full service corporate and regulatory advice and counsel with regard to navigation of OPO mergers;
- **Vendor Agreements and Provider MOUs:** Drafting and negotiating vendor agreements, including those related to transportation, tissue processor, information technology, and Normothermic Regional Perfusion, as well as required hospital/OPO and transplant center/OPO memoranda of understanding;
- **Audits and Risk Mitigation:** Conducting mock audits to identify areas for improvement;
- **Litigation:** Handling claims specific to providers and OPOs, including issues related to the Uniform Anatomical Gift Act;
- **Technology Integration:** Advising on the integration of electronic donor referral systems;

- **Policymaking and Legislation:** Drafting/revising proposed legislation and policies and advising clients on navigation of the same; and
- **Donor Registry:** Assisting clients regarding donor registry matters, including upholding First Person Authorization for donors and related information technology matters.



## Representative Matters

- Represented OPOs in an investigation by the Congressional House Oversight Subcommittee on Economic and Consumer Policy into allegations of poor performance, waste, and mismanagement in the organ donation and transplant industry.
- Represented an OPO in a Senate Finance Committee investigation into allegations regarding improper use of pancreata for research.
- Represented the surviving entity in the merger of two organ procurement organizations to form the largest OPO in the mid-Atlantic region.
- Counseled a transplant center regarding internal policies related to transplant candidate waitlist practices related to patient vaccination status and general patient noncompliance.
- Obtained dismissal of a case, which was upheld on appeal, brought against an OPO accused of improperly packaging and transporting a kidney for transplant, resulting in a leading opinion on the scope of the good faith immunity afforded to OPOs under the Uniform Anatomical Gift Act.
- Represented an OPO as part of a team at University of Maryland's Unmanned Aircraft Systems (UAS) and the University of Maryland Transplant Center to ensure FAA compliance, appropriate insurance coverage, and comprehensive consents in a first-ever successful mission to transport an organ for transplant via drone.
- Counseled a health care organization in drafting a letter to the North Carolina Attorney General's Office regarding a prior advisory opinion. As a result of the letter, the office reversed its position and retracted the prior opinion.