OPTN Organ Procurement & Transplantation Network

From OPTN President John Magee

Sept. 29, 2025

Dear OPTN Community,

Earlier this month, the Secretary of HHS announced an important step forward in our mission to ensure patient safety and maintain public trust. Specifically, the intent to decertify the Life Alliance Organ Recovery Agency (FLMP) organ procurement organization (OPO) due to longstanding noncompliance and threats to patient safety and public health. This decision represents not only a necessary enforcement action, but also progress in strengthening accountability, transparency, and trust in the system we are all committed to protecting.

This milestone was made possible by the leadership (both past and present) of the OPTN Board and the efforts of the MPSC and its volunteers. In May 2025, the OPTN Board wrote to the Secretary recommending action against FLMP after determining it posed ongoing risks to patient health and safety. That recommendation reflected our commitment to accountability and our duty to protect patients, and it laid the foundation for the Secretary's decision. Together, we have shown that this community has both the resolve and the responsibility to act when patient safety is at stake.

Highlights from the Announcement

- The OPTN recommended Secretary Kennedy take action to decertify the Life Alliance Organ Recovery Agency OPO after more than a decade of failed compliance, ongoing risks to patient safety, and the lack of a credible plan for improvement. HHS is prepared to take decisive action to protect patients and hold all OPTN members accountable.
- Secretary Kennedy directed the OPTN to establish a requirement that all OPOs appoint a Patient Safety Officer to oversee patient safety efforts. These officers will be responsible for monitoring and investigating patient safety events in real time, serving as the first point of contact for families, hospital partners, and HRSA, documenting and reporting incidents and adverse events to OPTN, leading root cause analyses, and ensuring corrective actions are implemented.

 The action builds on HHS's reforms to ensure fairness, trust, and transparency across the organ donation, procurement and transplantation system.

I am deeply grateful for the longstanding contributions of the OPTN Board, as well as the work of the MPSC and its volunteers, in making this milestone possible. You can read more detail about the announcement here: HHS to Close University of Miami's Failing Organ Agency | HHS.gov.

Details regarding next steps in ensuring continuation of operations for the region served by Life Alliance Organ Recovery Agency OPO will be announced. All involved are committed to ensuring donors and their families will continue to be served, and they will have the opportunity to fulfill their wish to donate organs for transplant.

Specific guidance regarding the OPO Patient Safety Officer will be forthcoming.

This action reminds us of the responsibility we share as a Board and as a community: to safeguard patients and families, to strengthen trust in the transplant system, and to ensure every action we take reflects fairness, safety, and transparency. By working collaboratively with HHS and our federal partners, we are not only addressing today's challenges but also shaping a stronger transplant system for the future. Together, we will continue refining a system that will serve patients and families for future generations.

Thank you,

John Magee, MD OPTN Board President

The <u>Organ Procurement and Transplantation Network</u> is a public-private partnership that manages the U.S. organ donation and transplant system to provide transplants and support transplant patients. It establishes and enforces national policies for organ allocation, ensuring fairness and efficiency in matching organs from deceased donors with transplant candidates.

