

## ATTACHMENT III

### Criteria for Organ Procurement Organizations

1. Have documentation demonstrating existence as a nonprofit entity that is exempt from Federal income taxation under section 501 of the Internal Revenue Code of 1986.
2. Have documentation demonstrating fiscal procedures in place to obtain payment for kidneys and non-renal organs provided to transplant centers.
3. Have an agreement (or application to the appropriate Medicare intermediary which must be approved within 120 days of UNOS approval) with the appropriate Medicare intermediary to be reimbursed under Medicare for the procurement of recovered organs.
4. Demonstrates that a defined service area exists, consistent with information submitted to the Center for Medicare/Medicaid Services (CMS), through the following information:

Names of counties or parishes served, or the state if an entire state is included.

  - Total population in service area (both the most recent official census as well as the latest intercensus estimate consistent with CMS).
  - The number/name of acute care hospitals in the service area with an operating room and the equipment and personnel to retrieve organs.
5. Have documented agreements for a working relationship with transplant centers and donor hospitals within the service area.
6. Have documented arrangements to coordinate its activities (per Code of Federal Regulations) with transplant centers in the area. These are to include arrangements for the preservation and transportation of donated organs to transplant centers.
7. Have a board of directors or an advisory board with a membership composition consistent with federal regulation requirements, with the authority to recommend policies relating to the donation, procurement, and equitable distribution of organs. Have a medical director who is a licensed physician who is responsible for the medical and clinical activities of the OPO.
8. Have documented arrangements with a CLIA certified laboratory (or certified laboratories), in the appropriate specialty or subspecialty or service, to provide donor screening and infection tests, including acquired immune deficiency virus, consistent with UNOS standards.
9. Have documented arrangements with an approved UNOS histocompatibility laboratory for the appropriate tissue typing of donated organs.
10. Submit evidence of a plan to equitably allocate donated organs among transplant patients that is consistent with the rules of UNOS.
11. An OPO must demonstrate they have policies and procedures that meet or exceed UNOS policies.
12. Have documented arrangements to cooperate with tissue banks for the recovery, processing, preservation, storage and distribution of tissues as may be appropriate to ensure that all usable tissue are obtained from potential donors.

13. Have documented procedures in place for ensuring the confidentiality of patient records for each donor recovered.
14. Submit evidence of a plan to conduct or participate in professional education concerning organ and tissue procurement, and public education concerning organ and tissue donation that includes the involvement of donor families, patients and recipients.
15. The OPO is required to have the technical ability to communicate the appropriate information in a timely fashion that is necessary to facilitate equitable distribution of organs.
16. An OPO must have a sufficient number of personnel to effectively recover donors in its service area. All member OPOs must have a director and such other staff, including an organ donation coordinator and an organ procurement specialist, necessary to recover and distribute organs according to UNOS policy.
17. All key personnel changes (executive director, medical director) must be reported to UNOS within 30 days of change. OPOs with key positions not filled within 6 months of vacancy must be reviewed by the Membership and Professional Standards Committee.
18. To maintain member status in UNOS, an OPO must continue to be re-certified as a qualified OPO by CMS (and designated as such by the Secretary of Health and Human Services) during their subsequent periodic reviews and provide documentation of recertification.
19. OPO's must submit to UNOS by January 15 of each year the: a.) number of donors procured; b.) the number of kidneys procured; c.) the number of kidneys transplanted; d.) the number of extrarenal organs procured; and e.) the number of extrarenal organs transplanted.