

### 3.1 DEFINITIONS.

The following terms are defined as having the following meanings for the purposes of these policies:

- 3.1.1 OPO.** An Organ Procurement Organization (OPO) is an organization, accepted as a Member, and authorized by the Centers for Medicare and Medicaid Services (CMS) to procure organs for transplantation. For each OPO, CMS defines a geographic procurement territory within which the OPO concentrates its procurement efforts. No OPO is limited to or granted exclusive procurement rights to procure organs in its territory.
- 3.1.2 Transplant Center.** A transplant center is a hospital that is a Member in which transplants are performed. A transplant center may also be called a transplant hospital. It is the responsibility of the transplanting surgeon at the transplant center receiving the organ offer for the surgeon's candidate to ensure medical suitability of donor organs for transplantation into the potential recipient, including compatibility of donor and candidate by ABO blood type and subtype (when used for allocation). Upon receipt of an organ, prior to implantation, the transplant center is responsible for verifying the recorded donor ABO and subtype (when used for allocation), with the recorded ABO and subtype (when used for allocation) of the intended recipient and UNOS Donor ID number. These actions must be documented and are subject to review upon audit.
- 3.1.3 Transplant Program.** A transplant center, or hospital, may have one or more transplant programs. Each program oversees transplantation of one or more organ types.
- 3.1.4 Waiting List.** The Waiting List is the computerized list of candidates who are waiting to be matched with specific donor organs in hopes of receiving transplants. Waiting List candidates are registered on the Waiting List by member transplant centers. The candidate's transplant program shall be responsible for ensuring the accuracy of candidate ABO data on the waiting list. Each transplant program shall implement and operate procedure for providing on-line verification of a candidate's ABO data on the waiting list against the source documents by an individual other than the person initially entering the candidate's ABO data in UNet<sup>SM</sup>. The transplant program shall maintain records documenting that such separate verification of the source documents against the entered ABO has taken place and make such documentation available for audit. Upon entry of the candidate's waitlist data, the candidate will be added to the waitlist but will not be listed as an active candidate until separate verification of the candidate's ABO data has taken place.
- 3.1.4.1** All transplant candidate interactions will be required to be completed through UNet<sup>SM</sup> by transplant programs. The Organ Center will facilitate candidate listings and modifications in the event of computer and/or Internet failure. When the Organ Center facilitates a candidate's listing or modification due to computer and/or Internet failure, the transplant center will be required to submit a statement explaining the event.
- 3.1.4.2** Each transplant candidate must be ABO typed on two separate occasions prior to listing. Two separate occasions is defined as two samples, taken at different times, sent to the same or different labs.
- 3.1.4.3** Transplant candidates shall only be listed on UNet<sup>SM</sup> with the candidate's actual blood type.

**NOTE:** UNet<sup>SM</sup> is the web-based electronic utility used by the OPTN contractor to conduct the business of the OPTN. UNet<sup>SM</sup> comprises the Match System, all software, applications and security architecture needed for the collection, modification, validation, reporting, management and redundancy of data associated with the tasks and activities of the OPTN.

- 3.1.5 Match System.** The Match System is the computerized algorithm used to prioritize candidates waiting for organs. It eliminates potential recipients whose size or ABO type is incompatible with that of a donor and then ranks those remaining potential recipients according to the ranking system approved by the Board.
- 3.1.6 Host OPO.** The Host OPO is the OPO which, having identified a potential organ donor, assumes responsibility for donor management and organ allocation.
- 3.1.7 Alternative Allocation System.** A type of variance that allows Members to allocate organs differently than the OPTN policies.
- 3.1.8 Variance.** An experimental policy that tests methods of improving allocation.
- 3.1.9 Open and Closed Variances.** An open variance is a variance that allows other Members to join it. A closed variance is a variance that is not open for other Members to join it.
- 3.1.10 Local and Alternative Local Unit (ALU).** A local unit is the geographic area for organ procurement and distribution. An alternative local unit is a type of variance that creates a distinct geographic area for organ procurement and distribution
- 3.1.11 Sharing Arrangement.** A type of variance that permits two or more OPOs to share organs.
- 3.1.12 Alternative Point Assignment Systems.** A type of variance that permits Members to assign points differently than the OPTN policies.
- 3.1.13 Definition of Directed Donation** – OPOs are permitted to allocate an organ(s) to a specific transplant candidate named by the person(s) who authorized the donation unless prohibited by state law. All recipients of a deceased donor organ(s) from a directed donation must be added to the waiting list prior to transplantation.

When the candidate does not appear on at least one of the deceased donor's match runs for at least one organ type, the transplant center must document the reason why the candidate does not appear and ensure that the organ is safe and appropriate for the candidate. The transplant center must maintain all related documentation and provide written justification to the OPTN contractor upon request. The written justification must include:

- the rationale for transplanting the candidate who did not appear on the match run;
- the reason the candidate did not appear on the match run;
- the center is willing to accept an ECD or DCD organ, as applicable; and
- documentation that the transplant center verified suitability between the donor organ and recipient prior to transplant in at least, but not limited to, the following areas as applicable to each organ type:
  - ABO;
  - ABO subtype when used for allocation;
  - Serologies;
  - Donor HLA and candidate's unacceptable antigens;
  - Height; and
  - Weight.