

## 42 C.F.R. § 486.302

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### Definitions.

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As used in this subpart, the following definitions apply:

*Adverse event* means an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof. As applied to OPOs, adverse events include but are not limited to transmission of disease from a donor to a beneficiary, avoidable loss of a medically suitable potential donor for whom consent for donation has been obtained, or delivery to a transplant center of the wrong organ or an organ whose blood type does not match the blood type of the intended beneficiary.

*Agreement cycle* refers to the time period of at least 4 years when an agreement is in effect between CMS and an OPO.

*Assessment period* is a 12-month period in which an OPO's outcome measures will be evaluated for performance. The final assessment period is the 12-month assessment period used to calculate outcome measures for re-certification.

*Certification* means a CMS determination that an OPO meets the requirements for certification at § 486.303.

*Death record review* means an assessment of the medical chart of a deceased patient to evaluate potential for organ donation.

*Death that is consistent with organ donation* means all deaths from the state death certificates with the primary cause of death listed as the ICD-10-CM codes I20-I25 (ischemic heart disease); I60-I69 (cerebrovascular disease); V-1-Y89 (external causes of death): Blunt trauma, gunshot wounds, drug overdose, suicide, drowning, and asphyxiation.

*Decertification* means a CMS determination that an OPO no longer meets the requirements for certification at § 486.303.

*Designated requestor or effective requestor* is an individual (generally employed by a hospital), who is trained to handle or participate in the donation consent process. The designated requestor may request consent for donation from the family of a potential donor or from the individual(s) responsible for making the donation decision in circumstances permitted under State law, provide information about donation to the family or decision-maker(s), or provide support to or collaborate with the OPO in the donation consent process.

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