

§ 486.301 Basis and scope.

(a) *Statutory basis.* (1) Section 1138(b) of the Act sets forth the requirements that an organ procurement organization (OPO) must meet to have its organ procurement services to hospitals covered under Medicare and Medicaid. These include certification as a “qualified” OPO and designation as the OPO for a particular service area.

(2) Section 371(b) of the Public Health Service Act sets forth the requirements for certification and the functions that a qualified OPO is expected to perform.

(3) Section 1102 of the Act authorizes the Secretary of Health and Human Services to make and publish rules and regulations necessary to the efficient administration of the functions that are assigned to the Secretary under the Act.

(4) Section 1871 of the Act authorizes the Secretary to prescribe regulations as may be necessary to carry out the administration of the Medicare program under title XVIII.

(b) *Scope.* This subpart sets forth—

(1) The conditions and requirements that an OPO must meet;

(2) The procedures for certification and designation of OPOs; and

(3) The terms of the agreement with CMS and the basis for and the effect of de-certification.

(4) The requirements for an OPO to be re-certified.

§ 486.302 Definitions.

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–I–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.

Designation means CMS assignment of a geographic service area to an OPO. Once an OPO is certified and assigned a geographic service area, organ procurement costs of the OPO are eligible for Medicare and Medicaid payment under section 1138(b)(1)(F) of the Act.

Donation rate is the number of donors as a percentage of the donor potential.

Donation service area (DSA) means a geographical area of sufficient size to ensure maximum effectiveness in the procurement and equitable distribution of organs and that either includes an entire metropolitan statistical area or does not include any part of such an

area and that meets the standards of this subpart.

Donor means a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is transplanted. An individual also would be considered a donor if only the pancreas is procured and is used for research or islet cell transplantation.

Donor after cardiac death (DCD) means an individual who donates after his or her heart has irreversibly stopped beating. A donor after cardiac death may be termed a non-heartbeating or asystolic donor.

Donor document means any documented indication of an individual's choice regarding his or her wishes concerning organ and/or tissue donation that was made by that individual or another authorized individual in accordance with any applicable State law."

Donor potential is the number of inpatient deaths within the DSA among patients 75 and younger with a primary cause of death that is consistent with organ donation. For OPOs servicing a hospital with a waiver under § 486.308(e), the donor potential of the county for that hospital will be adjusted using the proportion of Medicare beneficiary inpatient deaths in the hospital compared with the total Medicare beneficiary inpatient deaths in the county.

Entire metropolitan statistical area means a metropolitan statistical area (MSA), a consolidated metropolitan statistical area (CMSA), or a primary metropolitan statistical area (PMSA) listed in the State and Metropolitan Area Data Book published by the U.S. Bureau of the Census. CMS does not recognize a CMSA as a metropolitan area for the purposes of establishing a geographical area for an OPO.

Kidney transplantation rate is the number of kidneys transplanted from kidney donors in the DSA as a percentage of the donor potential.

Lowest rate among the top 25 percent will be calculated by taking the number of total DSAs in the time period identified for establishing the threshold rate. The total number of DSAs will be multiplied by 0.25 and rounded to the closest integer (0.5 will round to

the higher integer). The donation rates and organ transplantation rates in each DSA will be separately ranked and the threshold rate will be the rate that corresponds to that integer when counting down the ranking.

Open area means an OPO service area for which CMS has notified the public that it is accepting applications for designation.

Organ means a human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine). The pancreas counts as an organ even if it is used for research or islet cell transplantation.

Organ type	Number of organs transplanted
(1) Right or Left Kidney	1
(2) Right and Left Kidney	2
(3) Double/En-Bloc Kidney	2
(4) Heart	1
(5) Intestine	1
(6) Intestine Segment 1 or Segment 2	1
(7) Intestine Segment 1 and Segment 2	2
(8) Liver	1
(9) Liver Segment 1 or Segment 2	1
(10) Liver Segments 1 and Segment 2	2
(11) Right or Left Lung	1
(12) Right and Left Lung	2
(13) Double/En-bloc Lung	2
(14) Pancreas (transplanted whole, research, islet transplant)	1
(15) Pancreas Segment 1 or Segment 2	1
(16) Pancreas Segment 1 and Segment 2	2

Organ procurement organization (OPO) means an organization that performs or coordinates the procurement, preservation, and transport of organs and maintains a system for locating prospective beneficiaries for available organs.

Organ transplantation rate is the number of organs transplanted from donors in the DSA as a percentage of the donor potential. Organs transplanted into patients on the OPTN waiting list as part of research are included in the organ transplantation rate. The organ transplantation rate will be risk-adjusted for the average age of the donor potential using the following methodology:

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(1) The age groups used for the adjusted transplantation rates are: <1, 1–5, 6–11, 12–17, 18–24, 25–29, 30–34, 35–39, 40–44, 45–49, 50–54, 55–59, 60–64, 65–69, 70–75.

(2) Calculate a national age-specific transplantation rate for each age group.

An expected transplantation rate for each OPO is calculated as $\Sigma(g=1)Gdg \cdot Rg / \Sigma dg$, where dg is the number of potential donors in the OPO in age group g , Rg is the age-specific national transplantation rate in age group g , and Σdg is the OPO's total number of individuals in the donor potential. This can be interpreted as the overall expected transplantation rate for an OPO if each of its age-specific transplantation rates were equal to the national age-specific.

(3) Calculate the age-adjusted organ transplantation rate as $(O/E) \cdot P$, where O is the OPO's observed unadjusted transplantation rate, E is the expected transplantation rate calculated in Step 2, and P is the unadjusted national transplantation rate.

Re-certification cycle means the 4-year cycle during which an OPO is certified.

Transplant hospital means a hospital that provides organ transplants and other medical and surgical specialty services required for the care of transplant patients. There may be one or more types of organ transplant centers operating within the same transplant hospital.

Urgent need occurs when an OPO's noncompliance with one or more conditions for coverage has caused, or is likely to cause, serious injury, harm, impairment, or death to a potential or actual donor or an organ beneficiary.

[71 FR 31046, May 31, 2006, as amended at 77 FR 29031, May 16, 2012; 81 FR 79880, Nov. 14, 2016; 84 FR 61492, Nov. 12, 2019; 85 FR 77947, Dec. 2, 2020]

REQUIREMENTS FOR CERTIFICATION AND DESIGNATION

§ 486.303 Requirements for certification.

In order to be certified as a qualified organ procurement organization, an organ procurement organization must:

(a) Have received a grant under 42 U.S.C. 273(a) or have been certified or

re-certified by the Secretary within the previous 4 years as being a qualified OPO.

(b) Be a non-profit entity that is exempt from Federal income taxation under section 501 of the Internal Revenue Code of 1986.

(c) Have accounting and other fiscal procedures necessary to assure the fiscal stability of the organization, including procedures to obtain payment for kidneys and non-renal organs provided to transplant hospitals.

(d) Have an agreement with CMS, as the Secretary's designated representative, to be reimbursed under title XVIII for the procurement of kidneys.

(e) Have been re-certified as an OPO under the Medicare program from January 1, 2002 through December 31, 2005.

(f) Have procedures to obtain payment for non-renal organs provided to transplant centers.

(g) Agree to enter into an agreement with any hospital or critical access hospital in the OPO's service area, including a transplant hospital that requests an agreement.

(h) Meet the conditions for coverage for organ procurement organizations, which include both outcome and process performance measures.

(i) Meet the provisions of titles XI, XVIII, and XIX of the Act, section 371(b) of the Public Health Services Act, and any other applicable Federal regulations.

§ 486.304 Requirements for designation.

(a) Designation is a condition for payment. Payment may be made under the Medicare and Medicaid programs for organ procurement costs attributable to payments made to an OPO by a hospital only if the OPO has been designated by CMS as an OPO.

(b) An OPO must be certified as a qualified OPO by CMS under 42 U.S.C. 273(b) and § 486.303 to be eligible for designation.

(c) An OPO must enter into an agreement with CMS in order for the organ procurement costs attributable to the OPO to be reimbursed under Medicare and Medicaid.