

ORGAN PROCUREMENT ORGANIZATION
OUTCOME REQUIREMENTS**§ 486.318 Condition: Outcome measures.**

(a) With the exception of OPOs operating exclusively in non-contiguous U.S. states, commonwealths, territories, or possessions, an OPO must meet all 3 of the following outcome measures:

(1) The OPO's donation rate of eligible donors as a percentage of eligible deaths is no more than 1.5 standard deviations below the mean national donation rate of eligible donors as a percentage of eligible deaths, averaged over the 4 years of the re-certification cycle. Both the numerator and denominator of an individual OPO's donation rate ratio are adjusted by adding a 1 for each donation after cardiac death donor and each donor over the age of 70;

(2) The observed donation rate is not significantly lower than the expected donation rate for 18 or more months of the 36 months of data used for re-certification, as calculated by the SRTR;

(3) At least 2 out of the 3 following yield measures are no more than 1 standard deviation below the national mean, averaged over the 4 years of the re-certification cycle:

(i) The number of organs transplanted per standard criteria donor, including pancreata used for islet cell transplantation;

(ii) The number of organs transplanted per expanded criteria donor, including pancreata used for islet cell transplantation; and

(iii) The number of organs used for research per donor, including pancreata used for islet cell research.

(b) For OPOs operating exclusively in non-contiguous U.S. states, commonwealths, territories, and possessions, the OPO outcome measures are as follows:

(1) The OPO's donation rate of eligible donors as a percentage of eligible deaths is no more than 1.5 standard deviations below the mean national donation rate of eligible donors as a percentage of eligible deaths, averaged over the 4 years of the re-certification cycle. Both the numerator and denominator of an individual OPO's donation

rate ratio are adjusted by adding a 1 for each donation after cardiac death donor and each donor over the age of 70;

(2) The observed donation rate is not significantly lower than the expected donation rate for 18 or more months of the 36 months of data used for re-certification, as calculated by the SRTR;

(3) At least 2 out of the 3 following are no more than 1 standard deviation below the national mean:

(i) The number of kidneys transplanted per standard criteria donor;

(ii) The number of kidneys transplanted per expanded criteria donor; and

(iii) The number of organs used for research per donor, including pancreata recovered for islet cell transplantation.

(c) Data for the outcome measures.

(1) An OPO's performance on the outcome measures is based on 36 months of data, beginning with January 1 of the first full year of the re-certification cycle and ending 36 months later on December 31, 7 months prior to the end of the re-certification cycle.

(2) If an OPO takes over another OPO's service area on a date later than January 1 of the first full year of the re-certification cycle so that 36 months of data are not available to evaluate the OPO's performance in its new service area, we will not hold the OPO accountable for its performance in the new area until the end of the following re-certification cycle when 36 months of data are available.

ORGAN PROCUREMENT ORGANIZATION
PROCESS PERFORMANCE MEASURES**§ 486.320 Condition: Participation in Organ Procurement and Transplantation Network.**

After being designated, an OPO must become a member of, participate in, and abide by the rules and requirements of the OPTN established and operated in accordance with section 372 of the Public Health Service Act (42 U.S.C. 274). The term "rules and requirements of the OPTN" means those rules and requirements approved by the Secretary. No OPO is considered out of compliance with section 1138(b)(1)(D) of the Act or this section until the Secretary approves a determination that