
42 C.F.R. § 486.318

Condition: Outcome measures.

(a) With the exception of OPOs operating exclusively in noncontiguous States, Commonwealths, Territories, or possessions, an OPO must meet two out of the three 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) The OPO data reports, averaged over the 4 years of the recertification cycle, must meet the rules and requirements of the most current OPTN aggregate donor yield measure.

(i) The initial criteria used to identify OPOs with lower than expected organ yield, for all organs as well as for each organ type, will include all of the following:

(A) More than 10 fewer observed organs per 100 donors than expected yield (Observed per 100 donors—Expected per 100 donors < -10);

(B) A ratio of observed to expected yield less than 0.90; and

(C) A two-sided p-value is less than 0.05.

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

(4) The outcome measures described in § 486.318(a)(1) through (3) are effective until July 31, 2022.

(b) For OPOs operating exclusively in noncontiguous States, Commonwealths, Territories, and possessions, an OPO must meet two out of the three 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;

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