



**ASSOCIATION OF ORGAN PROCUREMENT ORGANIZATIONS**  
Saving and improving lives through organ, eye, and tissue donation

## AOPO Concerns with Proposed Rule Metrics

AOPO and the Organ Procurement Organization (OPO) community supports valid and continually improving performance metrics, that are based on sound data. Unfortunately, the proposed metrics fail to meet these standards in the following ways:

### 1) Performance Threshold

- a. Under the proposed rule, the bar to “pass” is arbitrarily set at the top 25<sup>th</sup> percentile without supporting rationale ensuring 75% of OPOs would not meet the metrics and could be subject to decertification.
- b. Decertifying up to 75% of OPOs in a given year would destabilize the system without an identified path for OPO performance improvement potentially leading to loss of lives.

**Recommendation:** Establish a performance threshold for the donation and transplantation rate metrics based on a specified standard deviation from the mean.

**Rationale:** Using a standard deviation performance threshold would more accurately and fairly assess OPO performance. It balances the need to incentivize continual performance improvement while establishing a rational basis for the threshold as supported by the data and valid statistical methodology.

### 2) Use of Death Certificates to Calculate Donor Potential

- a. Studies show that 30% to 60% of death certificates inaccurately report cause of death.
- b. Death certificates do not necessarily reflect whether a patient was eligible for donation. The certificates show primary cause of death but inconsistently document secondary conditions, such as if the deceased person was COVID-19 positive or had metastatic cancer, which would make them ineligible for donation.

**Recommendation:** Use inpatient ventilated deaths as the data set for donation rates.

**Rationale:** A potential donor must be on a ventilator in a hospital at the time of death for organ donation to occur. The calculation of a donation rate should include only these inpatients for the most accurate performance metric.

### 3) The Organ Transplant Metric Essentially Duplicates the Donation Rate Metric

- a. As both metrics share the same denominator, i.e. a calculation of donor potential based on death certificates, in essence both metrics measure the same thing and in effect there is only one OPO performance measure not two.

**Recommendation:** Retain the current Observed to Expected (O:E) Yield measure as the measure of organ transplantation rates.

**Rationale:** The observed versus expected ratio calculates the number of organs expected to be transplanted from a given donor (based upon data from actual donors) and compares it to the number of organs the OPO actually provides for transplant. If the ratio is 1.0, the OPO is performing as expected, if the ratio is > 1.0 the OPO is exceeding expectation, and if the ratio is < 1.0 the OPO is performing below expectation. Retaining this metric would also satisfy the statutory requirement for OPOs to be evaluated based on multiple metrics. *The data is independently reported, verifiable, calculated, and widely supported by all stakeholders in the donation and transplantation community.*

**CALL TO ACTION: Contact HHS to communicate these concerns with the proposed rule metrics.**