



Organ Procurement Organization Information and Listening Session



October 11, 2022

Top 3 Most Frequently Cited Standard Level Deficiency in 2022

Z085 - ADMINISTRATION AND GOVERNING BODY

- While an OPO may have more than one board, the OPO must have an advisory board that meets both the authority and membership requirements.

Z094 - ADMINISTRATION AND GOVERNING BODY

- The OPO must have bylaws for each of its board(s) that address potential conflicts of interest, length of terms, and criteria for selecting and removing members.

Z191 - DONATION AFTER CARDIAC DEATH

- Criteria for declaration of death and the time period that must elapse prior to organ recovery.

Next steps for 2026 Recertification

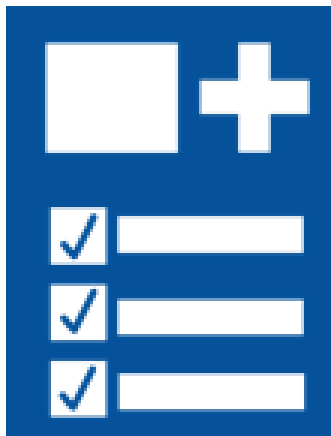
CMS is initiating additional oversight as a result of the new performance measures that will be subject to enforcement in the next Recertification cycle (2026).

CMS will review the release of the annual performance measures for each OPO.

**interim assessment years are 2023, 2024 and 2025; 2026 is the final assessment year.*

CMS will initiate contact with any OPOs noted with a decline in performance. This contact will be utilized to assess and identify any potential concerns regarding the OPO's Quality Assessment Performance Improvement (QAPI) program.

Next steps will be determined- which could include an *unannounced* onsite survey.





CMS/OPO Information/Listening Session

Preparing for the 2026 Recertification Cycle (2022-2026)

October 12, 2022

§486.318 Condition: Outcome Measures

2026 Survey Cycle

Enforcement of two newly defined outcome measures in the final rule and stratification:

- **Donation Rate:**
 - calculated as the actual OPO procurement (reported by the OPO to the OPTN) divided by the donor potential for the DSA (as reported by the MCOD)
- **Transplantation Rate:**
 - The organ transplantation rate for OPOs, except for the OPO servicing the Hawaii DSA, is calculated as the number of organs transplanted from donors in the DSA as a percentage of the donor potential. This rate is adjusted for the average age of the donor potential.
 - The kidney transplantation rate for the OPO servicing the Hawaii DSA is calculated as the number of kidneys transplanted in the DSA as a percentage of the donor potential. This rate is unadjusted.
- **Performance Tiers (Based on the donation and transplant rates):**
 - **Tier 1;** top 25%,
 - **Tier 2;** below top 25% but above median
 - **Tier 3;** falling below the median on either rate

Re-certification/Decertification and Competition

(Beginning August 1, 2022)

Re-certification/decertification standards

- **Tier 1:** OPO re-certified for four years and may compete for any open DSA
- **Tier 2:** OPO must compete to retain its DSA, and may compete for other open DSAs
- **Tier 3:** OPO is de-certified; cannot compete for any DSA (may appeal its decertification)

To compete, an OPO must meet:

- Requirements for Certification (42 CFR 486.303)
- Performance requirements for Tier 1 or Tier 2 (42 CFR 486.318)
- Conditions for Coverage (CfCs) at 486.320 through 486.360

Timelines for 2026 Recertification

OPOs received
Agreement letters for
the 2026 certification
cycle

OPOs receive
Annual Outcome
Reports each
spring (2023-2026)

Distribution of
Agreement Letters for
the 2030 certification
cycle

(Implementation of Final Rule Aug 1, 2022)

Survey Cycle 2026

(Jan.-July '26)