

Hospitals Transplant Centers – 1.00
Top Nine Federal Deficiencies
(01-01-14 through 12-31-14)

- 482.68 Special Requirements for Transplant Centers
- 482.82 Data Submit/Experience/Outcomes – Reapproval
- 482.82(c)(3) Outcome: Patient/Graft Survival – Reapproval
- 482.96 Quality Assessment/Performance Improvement
- 482.96(a) Components of QAPI Program
- 482.96(a) Actions to Improve Performance Tracking
- 482.96(b)(1) Adverse Events
- 482.96(b)(2) Analysis/Documentation of Adverse Event
- 482.96(b)(2) Effect Changes to Prevent Repeat Incidents

0001:

A transplant center located within a hospital that has a Medicare provider agreement must meet the conditions of participation specified in §482.72 through §482.104 in order to be granted approval from CMS to provide transplant services.

(a) Unless specified otherwise, the conditions of participation at §482.72 through §482.104 apply to heart, heart-lung, intestine, kidney, liver, lung, and pancreas centers.

(b) In addition to meeting the conditions of participation specified in §482.72 through §482.104, a transplant center must also meet the conditions of participation specified in §482.1 through §482.57.

0041:

Except as specified in paragraph (d) of this section and §488.61 of this chapter, transplant centers must meet all data submission, clinical experience, and outcome requirements in order to be re-approved.

0045:

CMS will not consider a center's patient and graft survival rates to be acceptable if: (i) A center's observed patient survival rate or observed graft survival rate is lower than its expected patient survival rate and graft survival rate; and (ii) All three of the following thresholds are crossed over: (A) The one-sided p-value is less than 0.05, (B) The number of observed events (patient deaths or graft failures) minus the number of expected events is greater than 3, and (C) The number of observed events divided by the number of expected events is greater than 1.5.

0099:

Transplant centers must develop, implement, and maintain a written, comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all transplantation services, including services provided under contract or arrangement.

0100:

The transplant center's QAPI program must use objective measures to evaluate the center's performance with regard to transplantation activities and outcomes. Outcome measures may include, but are not limited to, patient and donor selection criteria, accuracy of the waiting list in accordance with the OPTN waiting list requirements, accuracy of donor and recipient matching, patient and donor management, techniques for organ recovery, consent practices, patient education, patient satisfaction, and patient rights.

0101:

The transplant center must take actions that result in performance improvements and track performance to ensure that improvements are sustained.

0102:

A transplant center must establish and implement written policies to address and document adverse events that occur during any phase of an organ transplantation case. The policies must address, at a minimum, the process for the identification, reporting, analysis, and prevention of adverse events.

0103:

The transplant center must conduct a thorough analysis of and document any adverse event .

0104:

The transplant center must utilize the adverse event analysis to effect changes in the transplant center's policies and practices to prevent repeat incidents.