

GLOSSARY OF COMMONLY USED TERMS

ALJ: Administrative Law Judge.

Approval based on Mitigating Factors: Centers may request that CMS consider mitigating factors in the initial or re-approval process if the center does not meet a CoP. This procedure is NOT the same as an appeal of the deficiencies cited in the CMS Form 2567.

CMS: Centers for Medicare & Medicaid Services, formerly the Health Care Financing Administration (HCFA).

CMS Form 2567: Statement of Deficiencies and Plan of Correction; if a survey reveals deficiencies, will be sent to center within 10 days of completion of on-site survey.

CAP: Corrective Action Plan.

Condition-Level Deficiency: Based on specific criteria, but generally occurs when a center fails to meet a CoP.

CO: CMS' Central Office, located in Baltimore, Maryland.

CoP: Conditions of Participation. Certain standards and conditions that transplant centers must meet in order to be eligible to participate in the Medicare program.

Department of Health and Human Services (DHHS): Through the Centers for Medicare & Medicaid Services, DHHS administers the Medicare and Medicaid programs, and is the federal agency primarily concerned with healthcare fraud. Also referred to as HHS.

National Contractor: Centers not surveyed by a SA will be surveyed by a National Contractor.

NCD: national coverage determination.

OPTN: Organ Procurement and Transplantation Network.

PoC: Plan of Correction.

RO: CMS Regional Office. The ten ROs are located in: Boston, MA (Region 1); New York, NY (Region 2); Philadelphia, PA (Region 3); Atlanta, GA (Region 4); Chicago, IL (Region 5); Dallas, TX (Region 6); Kansas City, MO (Region 7); Denver, CO (Region 8); San Francisco, CA (Region 9); and Seattle, WA (Region 10).

SA: State Agency. Some States will survey their own transplant programs.

SRTR: Scientific Registry of Transplant Recipients.

SRTR Center Specific Report: A report generated by the SRTR that contains volume and outcome data for a specific transplant center.

Standard-Level Deficiency: Based on specific criteria, but generally occurs when a center fails to meet a discrete element of a CoP.

TPQR: Transplant Center Quarterly Report.

**Organ Transplant Survey
Requested Items for Each Program Type**

Hospital Name: _____ Survey Date: _____ to _____

Program Type: _____ Program Representative: _____

Lists Of Transplant Candidates, Recipients And Living Donors (by organ type)	Received
1. The transplant program's complete current active waiting number of individuals on the waiting list (does not include patients categorized as a "status 7, inactive" on the waiting list)	
2. List and number of persons evaluated but not placed on the waiting list within the past 12 months or after June 28, 2007, whichever date is most recent.	
3. List and number of all patients removed from the waiting list including the reason for the removal within the past 12 months, or after June 28, 2007, whichever date is most recent;	
4. List and number of the transplants performed including name, organ(s) transplanted, address, country of primary residence, resident alien or non-resident alien status, race and gender and date of transplant within the past three years, or after June 28, 2007, whichever date most recent;	
5. List and number of living donors including name, organ(s) transplanted and date of transplant (if applicable) within the past three years, or after June 28, 2007, whichever date most recent;	
6. List and number of transplant patients and donors that are <u>currently</u> an inpatients and the location of patient (unit, and floor);	
7. List and number of post-transplant patients and post-donation individuals that are scheduled for follow-up visits during the survey timeframe;	
List of Organ Recovery and Organ Offers	
8. List and number of all instances where the transplant program's own recovery team recovered the donor organ within the last three years or after June 28, 2007, whichever date is most recent. In each instance include the name of the transplant recipient. <i>[This list is not needed if the transplant program recovers <u>all</u> of the deceased donor organs for a given program type.]</i>	
9. List and number of the organs that the transplant program received offers for, and declined, and the reason for the declination;	

Program Administration: Policies, Procedures, Personnel, and QAPI	
10. The transplant program's policy and procedure manuals;	
11. A copy of the transplant program's written waiting list selection criteria for patients and donors (if applicable);	
12. A copy of the written material that is distributed to patients to explain the selection criteria (if different than #11);	
13. The hospital and transplant program's written agreement with their designated Organ Procurement Organization (OPO);	
14. An organizational chart of the transplant program;	
15. List of all transplant associated professional personnel and their titles;	
16. The curricula, training plan, and/or training schedule for personnel, (agenda, dates, evidence of attendance);	
17. On-call schedule for transplant surgeons and transplant physicians for the past 30 days;	
18. Any contracts with external parties that the hospital or transplant program have for services relevant to transplantation including: nursing, anesthesiology, immunology, pathology, surgery, internal medicine, infectious disease, pathology, radiology, blood banking and patient education;	
19. Any written transplant patient or living donor educational materials;	
20. The written copy of the Quality Assessment and Performance Improvement (QAPI) program;	
21. Any QAPI reports, records and minutes of QAPI committee meetings, or consultation reports about the QAPI program;	
22. Log of any reported adverse events for the past 12 months and corresponding documentation of the investigation and analysis of those events.	

Summary of Medicare Conditions of Participation for Transplant Centers

Title of condition of participation	Summary of requirements
Organ Procurement and Transplantation Network (OPTN) membership	The transplant program must be located in a hospital that is a member of the OPTN and that abides by the approved rules and requirements of the OPTN.
Notification to CMS	The transplant program must notify CMS of any significant changes related to the program or changes that could affect its compliance with the Medicare conditions of participation.
Pediatric transplants	A transplant program seeking to perform pediatric transplants must apply for specific approval to do so.
Data submission, clinical experience, and outcomes requirements for initial approval	<p>For initial Medicare approval:</p> <ul style="list-style-type: none"> • The transplant program must submit required data to the OPTN within a specified time frame. • Adult heart, liver, lung, and intestine transplant programs must generally perform 10 transplants over a 12-month period; adult kidney transplant programs must perform at least 3 transplants over a 12-month period prior to their request for initial approval. • Heart, liver, lung, and kidney transplant programs must have acceptable patient and graft (transplanted organ) survival rates.
Data submission, clinical experience, and outcomes requirements for reapproval	<p>To renew Medicare approval:</p> <ul style="list-style-type: none"> • The transplant program must submit required data to the OPTN within a specified time frame. • Adult heart, liver, lung, intestine, and kidney transplant programs must perform an average of 10 transplants per year. • Heart, liver, lung, and kidney transplant programs must have acceptable patient and graft survival rates.

Patient and living donor selection	<p>The transplant program must use written patient selection criteria and, if applicable, written living donor selection criteria. Patient selection criteria must assure a nondiscriminatory distribution of organs. Living donor selection criteria must be consistent with principles of medical ethics.</p> <p>The transplant program must have written protocols, including documentation of vital information, for recovery and receipt of organs from deceased donors and for living donor organ transplantation. The transplanting surgeon is responsible for ensuring the medical suitability of organs for transplantation into the intended recipient.</p>
Organ recovery and receipt	
Patient and living donor management	<p>The transplant program must have written patient and, if applicable, living donor management policies; keep patient waiting lists and medical records up to date; and provide social and nutritional services to patients and donors.</p> <p>The transplant program must develop, implement, and maintain a quality assessment and performance improvement program to monitor and evaluate its transplantation services.</p> <p>The transplant program must ensure that staff, including the program director, primary transplant surgeon and physician, clinical transplant coordinator, and living donor advocate are qualified and meet CMS-specified requirements.</p> <p>The hospital containing the transplant program must have a written agreement with an organ procurement organization designated by the Secretary of Health and Human Services.</p>
Quality assessment and performance improvement	<p>The transplant program must protect and promote patient and living donor rights through the implementation of informed consent policies, and must notify patients about factors that could affect patient access to transplantation, such as termination of Medicare approval or that the program is served by a single surgeon.</p>
Human resources	<p>Kidney transplant programs must furnish dialysis services and other care to end-stage renal disease patients.</p>
Organ procurement	
Patient and living donor rights	
Additional requirements for kidney transplant centers	