

Requirements for Transplant Programs to Notify CMS of Significant Program Changes

The regulation at 42 CFR §482.74 requires that a transplant program notify CMS immediately of any significant changes related to the transplant program or changes that could affect the program's compliance with the Medicare Conditions of Participation (as outlined under §482.72 through 482.104). The term "immediately" is considered to be at least within 7 business days of the change occurring.

These notification requirements became effective on June 28, 2007, the effective date of the regulation.

Significant changes or events in which CMS must be notified include:

- (1) *Staff Changes:* Changes in the transplant program's "primary transplant surgeon" or "primary transplant physician" as designated to the OPTN;"
- (2) *Changes to Clinical Experience and Outcomes:*

(Notification for this section is only required for programs that have already been approved under the transplant Conditions of Participation)

Any significant event that is expected to decrease the transplant program's number of transplants or survival rates that could result in the center being out of compliance with §482.82;

For programs subject to clinical experience (volume) requirements, examples of significant events include:

- The transplant program loses a sufficient number or type of personnel, which hinders or stops the ability of the program to perform transplants for a period exceeding 30 days; and could result in the clinical experience requirement (an average of 10 per year) not being met.
- The program loses access to any hospital resources or facilities, (e.g., lab services, damages to the physical plant or infrastructure) which seriously limits or prevents transplants from being performed for a period exceeding 30 days, and could result in the clinical experience requirement (an average of 10 per year) not being met.
- De-certification of the organ procurement organization (OPO) with which the transplant program has a contract and failure to enter into an agreement with another OPO for a period exceeding 30 days.

For programs subject to outcome requirements, examples of significant events include:

- Observable incidents of lower-than normal patient or graft survival rates for a period exceeding 30 days that could result in the transplant program not meeting the outcome requirements.
 - Changes in patient selection criteria, patient care practices or protocol that resulted in the unintended result of lowering patient or graft survival rates for a period exceeding 30 days that could result in the transplant program not meeting the outcome requirements.
- (3) Agreement with Organ Procurement Organization (OPO): Termination of an agreement between the hospital in which the transplant program is located and an OPO for the recovery and receipt of organs as required by §482.100; and
- (4) Inactivation: CMS must be notified when a transplant program inactivates its program. CMS will generally follow the OPTN rules set forth in Appendix B Section II (c) to determine what is considered an inactive program. There are a few differences from the OPTN rules regarding the inactivation of heart/lung programs which is not specified by the OPTN, and regarding pediatric programs which under this section follow the same rules as adult programs.

Transplant programs will be required to notify CMS when the program is either:

a) unable to serve patients, as a group, for a sustained and significant time period, where a period of 15 days or more is presumed to be sustained and significant, or

b) when no transplants have been performed for 90 days or more for heart, kidney, and liver programs and 6 months or more for pancreas, intestine/multivisceral, heart/lung and lung programs.

All notifications should be made in writing to Sherry Clark at sherry.clark@cms.hhs.gov or at the following mailing address or fax number:

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