

Organ Transplant Application Update

On March 30, 2007 the Department of Health and Human Services (DHHS) issued regulations authorizing the survey and certification of transplant programs. The Centers for Medicare & Medicaid Services (CMS) is the federal agency responsible for monitoring compliance with the Medicare Conditions of Participation. Prior to this new regulation, organ transplant programs were approved for Medicare participation either through ESRD Conditions for Coverage (renal programs) or National Coverage Decisions (non-renal). The new regulation established Conditions of Participation for all covered organ transplant programs.

All hospital transplant programs, approved for Medicare participation as of June 28, 2007 (approved either under the ESRD Conditions for Coverage or the National Coverage Decisions), must submit a request for new approval under the Conditions of Participation established by the new regulation. This request must be submitted to CMS **by December 26, 2007** (180 days from the effective date of the regulation.) Requests may be:

Mailed to:

Centers for Medicare and Medicaid Services
Attention: Sherry Clark
7500 Security Blvd.
Mailstop: S2-12-25
Baltimore, MD 21244

Faxed To:

(410) 786-0194
Attention: Sherry Clark

THERE IS NO OFFICIAL APPLICATION FORM. Each approved program should prepare a letter to CMS formally requesting Medicare approval for their program(s) under the new Hospital Conditions of Participation: Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplants. A hospital may submit one request for approval of all their transplant programs within one letter. However, the approval request must include all the essential information about **each** program. Please visit the CMS/Survey and Certification website at http://www.cms.hhs.gov/CertificationandCompliance/20_Transplant.asp for the specific information that must be included in an approval request. CMS is deleting the requirement that each program must submit a signed statement from the Organ Procurement Transplant Network (OPTN) verifying that the program is in compliance with all the data submission requirements of that organization. CMS will not require that this statement be submitted with provider letters requesting approval under the new Conditions of Participation. CMS has been working with the Health Resources and Services Administration (HRSA) and the United Network for Organ Sharing (UNOS, HRSA's contractor to operate the OPTN) to develop a report that would provide CMS with the percentage of required forms programs have submitted to the OPTN within the timeframe outlined in the regulation.

CMS will notify each applicant upon receipt of the approval request, will review the information submitted, and will schedule an on-site review of the program(s).

Please be advised that CMS will not launch the approval process until the program has entered a formal request for approval under new the Conditions of Participation and the necessary information concerning the program(s) has been received. If a program does not submit a request for approval under the new Conditions of Participation by December 28, 2007, CMS will conclude that the program no longer desires Medicare participation and will begin the process to withdraw Medicare approval.

If you have any questions concerning the approval requests, timelines for the regulation, the information that must be submitted with the approval request or the survey and certification process please direct your inquiries to Sherry Clark in the Survey and Certification Group at CMS at (410) 786-8476.