

Notice to Transplant Programs: Applications and Approval for Adult and Pediatric Transplant Programs

The Centers for Medicare & Medicaid Services (CMS) has revised its interpretation of the Conditions of Participation for transplant hospitals regarding the requirement for separate program approvals when transplant programs serve both adult (age 18 and over) and pediatric (under age 18) patients.

While a transplant program serving both populations may choose to apply for separate approvals as an adult and a pediatric program, they will not be required to do so. The revised interpretation states that a transplant program that performs 50% or more of their total transplants (in a 12-month period) on a given age group (majority), adult or pediatric, is not required to apply and be approved separately for the minority age group.

This means that pediatric programs that perform 50% or more of their transplants on pediatric patients in a 12-month period could also perform periodic transplants on adults (provided it is less than 50% of their total transplants), without the need to receive separate approval as an adult program. Consistent with the regulation, approved pediatric transplant programs will be exempt from the clinical experience (volume) requirements for both initial approval and re-approval.

Similarly, adult programs that perform 50% or more of their total transplants on adult patients in a 12-month period could perform periodic transplants on pediatric patients (provided it is less than 50% of total transplants), without the need to receive separate approval for a pediatric program.

During the survey process all patients served by the transplant program will be included within the review. For example, the onsite review for a pediatric program could include any adults served by that program in the sample of patient records, interviews, etc. The survey process would also assess the program's compliance with the requirements for data submission and the outcome report(s) that encompass all patients regardless of age that are served by that program. The outcomes measurements for adult and pediatric patients will be reviewed separately for all programs (except lung) using the methodology of the SRTR center-specific report. If a program chooses to apply as a single program for both adult and pediatric patients, any outcome requirements that apply must be met for patient and graft survival for both pediatric and adult patients served by that transplant program.

Please be advised that if CMS determines that a program has exceeded the 50% threshold for the age group for which it was not approved, either the current approval for the program will be removed and the program would be required to apply for approval under the new majority program, or the program may elect to seek two separate approvals (adult and pediatric).

Given this revised interpretation, any program that has already applied to CMS for an adult or pediatric transplant program and that would like to consolidate its application into a request for a single program (i.e., adult or pediatric) may contact Karen Tritz at (410) 786-8021 or Karen.tritz@cms.hhs.gov.