

Organ Transplants: Proposed Medicare rules for hospitals.

Blood type verification in 42 CFR 482.90 and 482.92.
Discussion and proposed rules on blood type verification are excerpted below from the Word file. Bold face added.

The entire proposed rule is on-line in text form at:

<http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/05-1696.htm>

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[Proposed Rules]
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Part III
Department of Health and Human Services
Centers for Medicare & Medicaid Services
42 CFR Parts 405, 482, and 488

Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants; Proposed Rule

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare and Medicaid Services
42 CFR Parts 405, 482, and 488

Medicare Program; Hospital Conditions of Participation:
Requirements for Approval and Re-Approval of Transplant Centers To
Perform Organ Transplants

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would set forth the requirements that heart, heart-lung, intestine, kidney, lung, and pancreas transplant centers must meet to participate as Medicare-approved transplant centers. These proposed revised requirements focus on an organ transplant center's ability to perform successful transplants and deliver quality patient care as evidenced by good outcomes and sound policies and procedures. We are proposing that approval, as determined by a center's compliance with the proposed data submission, outcome, and process requirements would be granted for 3 years. Every 3 years, approvals would be renewed for transplant centers that continue to meet these requirements. We are proposing these revised requirements to

ensure that transplant centers continually provide high-quality transplantation services in a safe and efficient manner.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on April 5, 2005.

Excerpted discussion of proposed rule, p 6159-60:

C. Proposed Process Requirements

1. Condition of Participation: Patient and Living Donor Selection (Proposed Section 482.90)

We also propose that before a transplant center places a patient on its waitlist, the candidate's medical record would have to contain documentation that the candidate's blood type has been determined. Requiring documentation

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of the candidate's blood type would ensure that transplant centers are verifying the accuracy of vital data necessary to match the transplant candidate to a potential donor. We are specifically requesting comments on this proposal.

Pg 6160:

2. Condition of Participation: Organ Recovery and Receipt (Proposed Section 482.92)

As reported in The Charlotte Observer, a recent death of a transplant recipient was caused by transplantation of organs from a donor of an incompatible blood type. The incident was attributed to a combination of system errors that occurred during the organ procurement, organ receipt, and transplant processes. Another death was attributed to a miscommunication of blood types between the center's laboratory and the transplant team (Grady, Denise and Lawrence K. Altman, ``Suit Says Transplant Error Was Cause in Baby's Death in August,' ' The New York Times, 12 March 2003, Section A, Page 23, Column 5). These two events might have been avoided if certain steps were actively taken to validate the ABO (i.e. blood type) compatibility and other key data elements.

Under the current policies for heart, liver and lung transplants and the current regulations for renal transplant centers, there are no provisions addressing procedures for transplant centers to ensure that donor organ and transplant recipient data are compared, or to prevent the transplantation of mismatched organs. The OPTN rules specify that an OPO with an organ available for transplantation must obtain a ``match run'' for that organ type from UNOS. The match run lists potential recipients on the waitlist who are the correct size and blood type to receive the organ that is available. The OPTN also requires the OPO to provide the transplant center with written documentation of the potential donor's age, sex, and race, appropriate laboratory values, blood type, ABO or HLA typing, vital signs, cause of brain death and diagnosis, and current medication and transfusion history. However, these OPTN policies are voluntary. **To prevent transplant mishaps caused by blood type mismatch, we propose that transplant centers would need**

to have written protocols for organ recovery and organ receipt. We propose that the protocols would have to ensure that the transplant center validates the donor's and the recipient's blood type and other vital data. Examples of vital data about the donor and the recipient that a transplant center should validate include, but are not limited to, appropriate laboratory values, vital signs, current medication and transfusion history. We also propose assigning responsibility for ensuring the medical suitability of donor organs for transplantation into the intended recipient to the transplanting surgeon, or the surgeon in the transplant center receiving the organ offer for his or her patient.

We propose that a center's protocols for organ recovery specify that a transplant center's organ recovery team would have to review and compare the recipient and donor data before recovery takes place. We also propose that when an organ arrives at the center, the transplanting surgeon and at least one other individual at the transplant center would have to verify that the donor's blood type and other vital data are compatible with transplantation of the intended recipient prior to transplantation. These verifications would ensure that transplant centers are actively taking steps to avoid transplantation of mismatched organs throughout the organ distribution process and would also prevent wastage of organs in the event a mismatch was not discovered until the organ(s) arrived at the transplant hospital.

We also propose that a center's protocols for organ recovery and receipt would have to ensure that the transplanting surgeon and at least one other individual at the transplant center verifies that the living donor's vital data (including blood type) are compatible for transplantation of the intended recipient, immediately before the removal of the living donor organ(s) and, if applicable, prior to the removal of the recipient's organ(s).

Proposed Rule, excerpts, p 6179-80:

Transplant Center Process Requirements

Sec. 482.90 Condition of participation: Patient and living donor selection.

The transplant center must use written patient selection criteria in determining a patient's suitability for placement on the waitlist or a patient's suitability for transplantation. If a center performs living donor transplants, the center also must use written donor selection criteria in determining the suitability of candidates for donation.

(a) Standard: Patient selection. Patient selection criteria must ensure fair and non-discriminatory distribution of organs.

(3) Before a transplant center places a transplant candidate on its waitlist, the candidate's medical record must contain documentation that the candidate's blood type has been determined.

Sec. 482.92 Condition of participation: Organ recovery and receipt.

Transplant centers must have written protocols for deceased organ recovery, organ receipt, and living donor transplantation to validate donor-recipient matching of blood types and other vital data. The transplanting surgeon at the transplant center is responsible for ensuring the medical suitability of donor organs for transplantation into the intended recipient.

(a) Standard: Organ recovery. A transplant center's organ recovery team must review and compare the donor-data with the recipient blood type and other vital data before organ recovery takes places.

(b) Standard: Organ receipt. When an organ arrives at the center, the

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transplanting surgeon and at least one other individual at the transplant center must verify that the donor's blood type and other vital data are compatible with transplantation of the intended recipient prior to transplantation.

(c) Standard: Living donor transplantation. If a center performs living donor transplants, the transplanting surgeon and at least one other individual at the center must verify that the living donor's blood type and other vital data are compatible with transplantation of the intended recipient immediately before the removal of the donor organ(s) and, if applicable, prior to the removal of the recipient's organ(s).