

[Code of Federal Regulations]
[Title 42, Volume 3]
[Revised as of October 1, 2004]
From the U.S. Government Printing Office via GPO Access
[CITE: 42CFR482.45]

[Page 496]

TITLE 42--PUBLIC HEALTH

CHAPTER IV--CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF
HEALTH AND HUMAN SERVICES (CONTINUED)

PART 482_CONDITIONS OF PARTICIPATION FOR HOSPITALS--Table of Contents

Subpart C_Basic Hospital Functions

Sec. 482.45 Condition of participation: Organ, tissue, and eye
procurement.

(a) Standard: Organ procurement responsibilities. The hospital must
have and implement written protocols that:

(1) Incorporate an agreement with an OPO designated under part 486
of this chapter, under which it must notify, in a timely manner, the
OPO

or a third party designated by the OPO of individuals whose death is
imminent or who have died in the hospital. The OPO determines medical
suitability for organ donation and, in the absence of alternative
arrangements by the hospital, the OPO determines medical suitability
for

tissue and eye donation, using the definition of potential tissue and
eye donor and the notification protocol developed in consultation with
the tissue and eye banks identified by the hospital for this purpose;

(2) Incorporate an agreement with at least one tissue bank and at
least one eye bank to cooperate in the retrieval, processing,
preservation, storage and distribution of tissues and eyes, as may be
appropriate to assure that all usable tissues and eyes are obtained
from

potential donors, insofar as such an agreement does not interfere with
organ procurement;

(3) Ensure, in collaboration with the designated OPO, that the
family of each potential donor is informed of its options to donate
organs, tissues, or eyes or to decline to donate. The individual
designated by the hospital to initiate the request to the family must
be

an organ procurement representative or a designated requestor. A
designated requestor is an individual who has completed a course
offered

or approved by the OPO and designed in conjunction with the tissue and
eye bank community in the methodology for approaching potential donor
families and requesting organ or tissue donation;

(4) Encourage discretion and sensitivity with respect to the
circumstances, views, and beliefs of the families of potential donors;

(5) Ensure that the hospital works cooperatively with the
designated

OPO, tissue bank and eye bank in educating staff on donation issues,
reviewing death records to improve identification of potential donors,

and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.

(b) Standard: Organ transplantation responsibilities. (1) A hospital in which organ transplants are performed must be a member of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274) and abide by its rules. The term ``rules of the OPTN'' means those rules provided for in regulations issued by the Secretary in accordance with section 372 of the PHS Act which are enforceable under 42 CFR 121.10. No hospital is considered to be out of compliance with section 1138(a)(1)(B) of the Act, or with the requirements of this paragraph, unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the hospital from the OPTN and has notified the hospital in writing.

(2) For purposes of these standards, the term ``organ'' means a human kidney, liver, heart, lung, or pancreas.

(3) If a hospital performs any type of transplants, it must provide organ-transplant-related data, as requested by the OPTN, the Scientific Registry, and the OPOs. The hospital must also provide such data directly to the Department when requested by the Secretary.

[63 FR 33875, June 22, 1998]