State of Idaho
DEPARTMENT OF HEALTH AND WELFARE
Division of Medicaid

BUREAU OF FACILITY STANDARDS

DIRK KEMPTHORNE
Governor
KARL B. KURTZ
Director
JOSEPH R. BRUNSON
Administrator

P.O. Box 83720
Boise, ID
83720-0036
(208)334-6626
Fax (208)364-1888

INFORMATIONAL LETTER #2000-4

DATE: March 30, 2000

TO: ALL HOSPITAL ADMINISTRATORS

FROM: LORETTA TODD, R.N., Interim Chief
Bureau of Facility Standards

SUBJECT: **CONDITION OF PARTICIPATION: ORGAN, TISSUE, AND EYE PROCEDUREMENT - REGULATIONS AND INTERPRETIVE GUIDELINES**

On June 22, 1998, a new requirement was added to the hospital Conditions of Participation (CoP). This requirement addresses the requirements related to organ, tissue, and eye procurement (42 CFR 482.45). Due to the complexity of implementing the new CoP, the Health Care Financing Administration (HCFA) delayed enforcement of the new CoP for approximately one (1) year. Thus, compliance for this CoP has been reviewed on recent hospital recertification surveys. In addition, on March 22, 2000, this office received instructions from HCFA to survey for this new CoP on any accredited or non-accredited hospital complaint survey.

The enclosed document includes the regulations and interpretive guidelines for the CoP to assist you toward compliance. I hope this information will be useful to you.

Should you have any questions regarding the enclosed information, please contact Sylvia Creswell, Non-Long Term Care Supervisor at (208) 334-6626 or via e-mail at creswsa@mmis.state.id.us

Loretta Todd

LORETTA TODD, R.N., Interim Chief
Bureau of Facility Standards

LT/nah
Enclosure
cc: Idaho Hospital Association

Medicare
State Operations Manual
Provider Certification

Department of Health and Human Services (DHHS)

HEALTH CARE FINANCING ADMINISTRATION (HCFA)

Transmittal 12

Date: OCTOBER 1999

HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
Appendix A	A-81 - A-84.4 (8 pp.)	A-81 - A-82 (2 pp.)

NEW/REVISED MATERIAL--EFFECTIVE DATE: NOVEMBER 29, 1999

Appendix A, Survey Procedures for Hospitals, is revised to include new procedures and clarifies issues based on the new condition of participation for Organ, Tissue, and Eye Procurement.

DISCLAIMER: **The revision date and transmittal number only apply to the redlined material. All other material was previously published in the manual and is only being reprinted.**

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FACILITY STANDARDS

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A237	(4) The hospital must maintain written evidence of regular inspection and approval by State or local fire control agencies.	Survey Procedures: §482.41(b)(4) Examine copies of inspection and approval reports from State and local fire control agencies.
A238	(c) Standard: Facilities. The hospital must maintain adequate facilities for its services.	
A239	(1) Diagnostic and therapeutic facilities must be located for the safety of patients.	Survey Procedures: §482.41(c)(1) Diagnostic and therapeutic facilities must be in rooms or areas specifically designed for the purpose intended. Check X-ray, physical therapy, and other specialized services for the appropriateness of the area for the service provided.
A240	(2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.	Survey Procedures: §482.41(c)(2) Talk to the person in charge of medical equipment and determine if there is an adequate repair/periodic maintenance program. There should be a regular periodic maintenance program for medical devices and equipment. A qualified individual such as a clinical or biomedical engineer should check the equipment periodically in accordance with the manufacturer's recommendations.
A241	(3) The extent and complexity of facilities must be determined by the services offered.	Survey Procedures: §482.41(c)(3) Verify through observation that the physical facilities are large enough and properly equipped for the scope of services provided and the number of patients served.

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A242	(4) There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.	Survey Procedures: §482.41(c)(4) Check that all food and medication preparation areas are well lighted. An appropriate number of refrigerators and/or heating devices should be provided to ensure that food and medicine do not spoil. Verify through observation that pharmaceuticals are stored at temperatures recommended by the product manufacturer. Food products should be stored appropriately. USDA Requirements: Refrigerator, 34-40 degrees Fahrenheit - best; 34-45 degrees Fahrenheit - allowable. Freezer, zero degrees Fahrenheit - best; plus 5 degrees Fahrenheit - allowable. State or local laws may impose more stringent requirements.
		(See Pages A-110 - A-113 for Interpretive Guidelines on §482.42, Condition of Participation - Infection Control)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A350	§482.45 Condition of participation: Organ, tissue, and eye procurement.	
A351	a) Standard: Organ procurement responsibilities. The hospital must have and implement written protocols that:	Survey Procedures and Probes §482.45(a) Verify by review that the hospital has organ procurement protocols that reflect the approval of the hospital's governing body. Have any revisions and/or modifications of the written protocols been approved by the hospital's medical staff and governing body? Are there any annotated references including the date of the last review session? Ensure through staff interviews that any revisions and/or modifications have been communicated to the staff, and that staff are aware of and understand the changes.
A352	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.	Interpretive Guidelines §482.45(a)(1) When death is imminent the hospital must make the referrals both before a potential donor is removed from a ventilator and while the potential donor's organs are still viable. Survey Procedures and Probes §482.45(a)(1) Verify by review that the hospital has an agreement with a designated Organ Procurement Organization (OPO). Verify that there is a policy in place that defines "imminent death" and that it ensures timely notification of the OPO. Verify implementation of the protocols by drawing a representative sample from a list of patients who have died in the hospital in the last six months. Verify that the agreement: o Specifies criteria for referral including the referral of all individuals whose death is imminent or who have died in the hospital; o Acknowledges the OPO's responsibility to determine medical suitability for organ donation. Unless the hospital has an alternative arrangement with a different tissue and/or

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A352 (Cont.)		eye bank, the OPO agreement acknowledges the OPO's responsibility to determine the medical suitability of tissue and/or eye donation, using the definition of the hospital designated tissue and/or eye bank for potential tissue and eye donor; o Specifies notification protocols developed by the OPOs in consultation with the hospital designated tissue and eye bank(s); o Provides for notification of each individual death in a timely manner to the OPO (or designated third party) in accordance with the terms of the agreements; and o Ensures that the designated requestor training program offered by the OPO has been developed in cooperation with and input from the tissue and eye bank designated by the hospital. NOTE: Timely notification means a hospital must contact the OPO by telephone as soon as possible after an individual has died, has been placed on a ventilator due to a severe brain injury, or who has been declared brain dead.
A353	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;	Interpretive Guidelines §482.45(a)(2) If a hospital wants to inform the OPO, tissue bank, and eye bank of a death by making only one call, the OPO, functioning as a gate keeper, is required to notify the tissue bank and eye bank selected by the hospital of the death, even if the OPO has its own tissue and eye recovery service. This agreement may be a singular one with an OPO that provides services for organ, tissue and eye, or a separate agreement with another tissue and/or eye bank outside the OPO, chosen by the hospital. The hospital may continue current successful direct arrangements with tissue and eye banks as long as the direct arrangement does not interfere with organ procurement. Survey Procedures and Probes §482.45(a)(2) Verify by review that the hospital has an agreement with a tissue and eye bank and that the agreement: o Specifies criteria for referral of all individuals who have died in the hospital; o Acknowledges the OPO's responsibility to determine medical suitability for tissue and eye donation, unless the hospital has an alternative arrangement with a different tissue and/or eye bank;

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A353 (Cont.)		o Specifies notification protocols developed by the OPOs in consultation with the hospital designated tissue and eye bank(s); o Provides for notification of each individual death in a timely manner (as defined by the hospital in conjunction with the OPO) to the OPO (or designated third party) in accordance with the terms of the agreements; o Ensures that the designated requestor training program offered by the OPO has been developed in cooperation with input from the tissue/or eye bank designated by the hospital. Verify compliance with the terms of the agreement when reviewing the representative sample drawn from a list of all patients who have died in the hospital in the last six months. If there is evidence that the OPO, tissue bank, or eye bank are not cooperating, how has the hospital attempted to resolve the issues?. If the hospital has been unable to resolve the issue, to whom have they reported the problem?
A354	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;	Survey Procedures and Probes §482.45(a)(3) Verify that the hospital ensures: o That individuals who approach the family are "designated requestors" or representatives of the OPO; o That the family is informed of options regarding organ/tissue donations; o That any "designated requestor" for organs has completed a training course either offered or approved by the OPO, which addresses methodology for approaching potential donor families; and o That any "designated requestor" for tissues or eyes has been trained to request tissues or eyes. What protocols are in place to ensure only designated requestors or representatives of the OPO approach families about donations? Review training schedules and personnel files to verify participation in the required training.

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A355	4) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;	Interpretive Guidelines §482.45(a)(4) Using discretion does not mean a judgment can be made by the hospital, that certain families should not be approached about donation (i.e., certain religious beliefs prohibit donation). Survey Procedures and Probes §482.45(a)(4) Review the in-service training program for those staff persons designated by the hospital to notify the family of its options. Review the facility complaint file for any relevant complaints.
A356	5) Ensure that the hospital works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues,	Survey Procedures and Probes §482.45(a)(5) How has the hospital assured that all appropriate staff have attended an educational program regarding donation issues and how to work with the OPO, tissue bank, and eye bank? Review in-service training schedules and attendance sheets. Review the education program content to ensure the following are included: o Consent process; o Importance of discretion and sensitivity; o Role of the designated requestor; o Transplantation and donation including pediatrics; o Quality improvement activities; and o Role of the organ procurement organization.
A357	reviewing death records to improve identification of potential donors, and	Survey Procedures and Probes §482.45(a)(5) Verify by review of policies and records that the hospital works with OPO, tissue bank, and eye bank in reviewing death records. Verify that the effectiveness of any protocols and policies is monitored as part of the hospital's quality improvement program.

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A357 (Cont.)		How will the effectiveness of the implemented changes be monitored and by whom? Validate that someone is identified to do the reviews and determine how often the reviews are to occur. Review the protocols that are in place to guide record reviews and analyses. Determine how confidentiality is ensured.
A358	maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.	Survey Procedures and Probes §482.45(a)(5) Determine by review, what procedures are in place to ensure potential donors are identified and declared dead by an appropriate practitioner in an acceptable time frame. Verify that there are procedures in place to ensure coordination between the facility staff and OPO staff in maintaining the potential donor.
A359	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.	Survey Procedures and Probes §482.45(b) If you have questions concerning the facility membership in the Organ Procurement and Transplantation Network; you may verify the membership by contacting the HCFA regional office or by calling the United Network for Organ Sharing (UNOS) at 1-804-330-8500.

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A359 (Cont.)	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.	Survey Procedures and Probes §482.45(b)(3) Verify by review, one year of reports submitted by the facility to the OPTN, the Scientific Registry, the OPOs, and any data submitted to the Department per request of the Secretary.