AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

(d) *Standard: Linen.* The organization has available at all times a quantity of linen essential for proper care and comfort of patients. Linens are handled, stored, processed, and transported in such a manner as to prevent the spread of infection.

(e) *Standard: Pest control.* The organization's premises are maintained free from insects and rodents through operation of a pest-control program.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, 2328, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

§ 485.727 Condition of participation: Disaster preparedness.

The organization has a written plan, periodically rehearsed, with procedures to be followed in the event of an internal or external disaster and for the care of casualties (patients and personnel) arising from a disaster.

(a) *Standard: Disaster plan.* The organization has a written plan in operation, with procedures to be followed in the event of fire, explosion, or other disaster. The plan is developed and maintained with the assistance of qualified fire, safety, and other appropriate experts, and includes:

(1) Transfer of casualties and records;

(2) The location and use of alarm systems and signals;

(3) Methods of containing fire;

(4) Notification of appropriate persons; and

(5) Evacuation routes and procedures.

(b) *Standard: Staff training and drills.* All employees are trained, as part of their employment orientation, in all aspects of preparedness for any disaster. The disaster program includes orientation and ongoing training and drills for all personnel in all procedures so that each employee promptly and correctly carries out his assigned role in case of a disaster.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988. Redesignated and amended at 60 FR 2326–2327, 2329, Jan. 9, 1995]

§ 485.729 Condition of participation: Program evaluation.

The organization has procedures that provide for a systematic evaluation of its total program to ensure appropriate utilization of services and to determine whether the organization's policies are followed in providing services to patients through employees or under arrangements with others.

(a) *Standard: Clinical-record review.* A sample of active and closed clinical records is reviewed quarterly by the appropriate health professionals to ensure that established policies are followed in providing services.

(b) *Standard: Annual statistical evaluation.* An evaluation is conducted annually of statistical data such as number of different patients treated, number of patient visits, condition on admission and discharge, number of new patients, number of patients by diagnosis(es), sources of referral, number and cost of units of service by treatment given, and total staff days or work hours by discipline.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326–2327, 2329, Jan. 9, 1995]

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

Subpart A—General Provisions

Sec.

486.1 Basis and scope.

Subpart B—[Reserved]

Subpart C—Conditions for Coverage: Portable X-Ray Services

486.100 Condition for coverage: Compliance with Federal, State, and local laws and regulations.
486.102 Condition for coverage: Supervision by a qualified physician.
486.104 Condition for coverage: Qualifications, orientation, and health of technical personnel.
486.106 Condition for coverage: Referral for service and preservation of records.
486.108 Condition for coverage: Safety standards.

486.110 Condition for coverage: Inspection of equipment.

Subpart D—Conditions for Coverage: Outpatient Physical Therapy Services Furnished by Physical Therapists in Independent Practice

486.150 Condition for coverage: General requirements.
486.151 Condition for coverage: Supervision.
486.153 Condition for coverage: Compliance with Federal, State, and local laws.
486.155 Condition for coverage: Plan of care.
486.157 Condition for coverage: Physical therapy services.
486.159 Condition for coverage: Coordination of services with other organizations, agencies, or individuals.
486.161 Condition for coverage: Clinical records.
486.163 Condition for coverage—physical environment.

Subparts E-F—[Reserved]

Subpart G—Conditions for Coverage: Organ Procurement Organizations

486.301 Basis and scope.
486.302 Definitions.
486.304 General requirements.
486.306 Qualifications for designation as an OPO.
486.307 OPO service area size designation and documentation requirements.
486.308 Condition: Participation in organ procurement and transplantation network.
486.310 Condition: Adherence to performance standards.
486.314 Effect of failure to meet requirements.
486.316 Designation of one OPO for each service area.
486.318 Changes in ownership or service area.
486.325 Termination of agreement with HCFA.
APPENDIX A TO SUBPART G OF PART 486—GUIDELINES FOR PREVENTING TRANSMISSION OF HUMAN IMMUNODEFICIENCY VIRUS THROUGH TRANSPLANTATION OF HUMAN TISSUE AND ORGANS

AUTHORITY: Sections 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provisions

§ 486.1 Basis and scope.

(a) *Statutory basis.* This part is based on the following sections of the Act:

1138(b)—for coverage of organ procurement services.

1861(p)—for coverage of outpatient physical therapy services furnished by physical therapists in independent practice.

1861(s) (3), (15), and (17)—for coverage of portable X-ray services.

(b) *Scope.* (1) This part sets forth the conditions for coverage of certain specialized services that are furnished by suppliers and that are not specified in other portions of this chapter.

(2) The conditions for coverage of other specialized services furnished by suppliers are set forth in the following regulations which, unless otherwise indicated, are part of this chapter:

(i) Ambulatory surgical center (ASC) services—Part 416.

(ii) Ambulance services—Part 410, subpart B.

(iii) ESRD services—Part 405, subpart U.

(iv) Laboratory services—Part 493.

(v) Mammography services—Part 410, subpart B (§ 410.34) and 21 CFR Part 900, subpart B, of the Food and Drug Administration regulations.

(vi) Rural health clinic and Federally qualified health center services—Part 491, subpart A.

[60 FR 50447, Sept. 29, 1995]

Subpart B—[Reserved]

Subpart C—Conditions for Coverage: Portable X-Ray Services

AUTHORITY: Secs. 1102, 1861(s) (3), (11) and (12), 1864, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x(s) (3), (11), and (12), 1395aa and 1395hh).

SOURCE: 34 FR 388, Jan. 10, 1969, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, Jan. 9, 1995.

§ 486.100 Condition for coverage: Compliance with Federal, State, and local laws and regulations.

The supplier of portable X-ray services is in conformity with all applicable Federal, State, and local laws and regulations.

(a) *Standard—licensure or registration of supplier.* In any State in which State or applicable local law provides for the licensure or registration of suppliers of

X-ray services, the supplier is (1) licensed or registered pursuant to such law, or (2) approved by the agency of the State or locality responsible for licensure or registration as meeting the standards established for such licensure or registration.

(b) *Standard—licensure or registration of personnel.* All personnel engaged in operating portable X-ray equipment are currently licensed or registered in accordance with all applicable State and local laws.

(c) *Standard—licensure or registration of equipment.* All portable X-ray equipment used in providing portable X-ray services is licensed or registered in accordance with all applicable State and local laws.

(d) *Standard—conformity with other Federal, State, and local laws and regulations.* The supplier of portable X-ray services agrees to render such services in conformity with Federal, State, and local laws relating to safety standards.

[34 FR 388, Jan. 10, 1969. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, Jan. 9, 1995; 60 FR 45086, Aug. 30, 1995]

§ 486.102 Condition for coverage: Supervision by a qualified physician.

Portable X-ray services are provided under the supervision of a qualified physician.

(a) *Standard—physician supervision.* The performance of the roentgenologic procedures is subject to the supervision of a physician who meets the requirements of paragraph (b) of this section and one of the following requirements is met:

(1) The supervising physician owns the equipment and it is operated only by his employees, or

(2) The supervising physician certifies annually that he periodically checks the procedural manuals and observes the operators' performance, that he has verified that equipment and personnel meet applicable Federal, State, and local licensure and registration requirements and that safe operating procedures are used.

(b) *Standard—qualifications of the physician supervisor.* Portable X-ray services are provided under the supervision of a licensed doctor of medicine or licensed doctor of osteopathy who is qualified by advanced training and experience in the use of X-rays for diagnostic purposes, i.e., he (1) is certified in radiology by the American Board of Radiology or by the American Osteopathic Board of Radiology or possesses qualifications which are equivalent to those required for such certification, or (2) is certified or meets the requirements for certification in a medical specialty in which he has become qualified by experience and training in the use of X-rays for diagnostic purposes, or (3) specializes in radiology and is recognized by the medical community as a specialist in radiology.

[34 FR 388, Jan. 10, 1969. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, Jan. 9, 1995; 60 FR 45086, Aug. 30, 1995]

§ 486.104 Condition for coverage: Qualifications, orientation and health of technical personnel.

Portable X-ray services are provided by qualified technologists.

(a) *Standard—qualifications of technologists.* All operators of the portable X-ray equipment meet the requirements of paragraph (a) (1), (2), or (3) of this section:

(1) Successful completion of a program of formal training in X-ray technology of not less than 24 months' duration in a school approved by the Council on Education of the American Medical Association or by the American Osteopathic Association, or have earned a bachelor's or associate degree in radiologic technology from an accredited college or university.

(2) For those whose training was completed prior to July 1, 1966, but on or after July 1, 1960: Successful completion of 24 full months of training and/or experience under the direct supervision of a physician who is certified in radiology by the American College of Radiology or who possesses qualifications which are equivalent to those required for such certification, and at least 12 full months of pertinent portable X-ray equipment operation experience in the 5 years prior to January 1, 1968.

(3) For those whose training was completed prior to July 1, 1960: Successful completion of 24 full months of training and/or experience of which at

least 12 full months were under the direct supervision of a physician who is certified in radiology by the American College of Radiology or who possesses qualifications which are equivalent to those required for such certification, and at least 12 full months of pertinent portable X-ray equipment operation experience in the 5 years prior to January 1, 1968.

(b) *Standard—personnel orientation.* The supplier of portable X-ray services has an orientation program for personnel, based on a procedural manual which is: Available to all members of the staff, incorporates relevant portions of professionally recognized documents, and includes instruction in all of the following:

(1) Precautions to be followed to protect the patient from unnecessary exposure to radiation;

(2) Precautions to be followed to protect an individual supporting the patient during X-ray procedures from unnecessary exposure to radiation;

(3) Precautions to be followed to protect other individuals in the surrounding environment from exposure to radiation;

(4) Precautions to be followed to protect the operator of portable X-ray equipment from unnecessary exposure to radiation;

(5) Considerations in determining the area which will receive the primary beam;

(6) Determination of the time interval at which to check personnel radiation monitors;

(7) Use of the personnel radiation monitor in providing an additional check on safety of equipment;

(8) Proper use and maintenance of equipment;

(9) Proper maintenance of records;

(10) Technical problems which may arise and methods of solution;

(11) Protection against electrical hazards;

(12) Hazards of excessive exposure to radiation.

(c) *Standard: Employee records.* Records are maintained and include evidence that—

(1) Each employee is qualified for his or her position by means of training and experience; and

(2) Employees receive adequate health supervision.

[34 FR 388, Jan. 10, 1969. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988; 60 FR 45086, Aug. 30, 1995]

§ 486.106 Condition for coverage: Referral for service and preservation of records.

All portable X-ray services performed for Medicare beneficiaries are ordered by a doctor of medicine or doctor of osteopathy and records are properly preserved.

(a) *Standard—referral by a physician.* Portable X-ray examinations are performed only on the order of a doctor of medicine or doctor of osteopathy licensed to practice in the State. The supplier's records show that:

(1) The X-ray test was ordered by a licensed doctor of medicine or doctor of osteopathy, and

(2) Such physician's written, signed order specifies the reason an X-ray test is required, the area of the body to be exposed, the number of radiographs to be obtained, and the views needed; it also includes a statement concerning the condition of the patient which indicates why portable X-ray services are necessary.

(b) *Standard—records of examinations performed.* The supplier makes for each patient a record of the date of the X-ray examination, the name of the patient, a description of the procedures ordered and performed, the referring physician, the operator(s) of the portable X-ray equipment who performed the examination, the physician to whom the radiograph was sent, and the date it was sent.

(c) *Standard—preservation of records.* Such reports are maintained for a period of at least 2 years, or for the period of time required by State law for such records (as distinguished from requirements as to the radiograph itself), whichever is longer.

[34 FR 388, Jan. 10, 1969. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, Jan. 9, 1995; 60 FR 45086, Aug. 30, 1995]

§ 486.108 Condition for coverage: Safety standards.

X-ray examinations are conducted through the use of equipment which is free of unnecessary hazards for patients, personnel, and other persons in the immediate environment, and through operating procedures which provide minimum radiation exposure to patients, personnel, and other persons in the immediate environment.

(a) *Standard—tube housing and devices to restrict the useful beam.* The tube housing is of diagnostic type. Diaphragms, cones, or adjustable collimators capable of restricting the useful beam to the area of clinical interest are used and provide the same degree of protection as is required of the housing.

(b) *Standard—total filtration.* (1) The aluminum equivalent of the total filtration in the primary beam is not less than that shown in the following table except when contraindicated for a particular diagnostic procedure.

Operating kVp	Total filtration (inherent plus added)
Below 50 kVp	0.5 millimeters aluminum.
50–70 kVp	1.5 millimeters aluminum.
Above 70 kVp	2.5 millimeters aluminum.

(2) If the filter in the machine is not accessible for examination or the total filtration is unknown, it can be assumed that the requirements are met if the half-value layer is not less than that shown in the following table:

Operating kVp	Half-value layer
50 kVp	0.6 millimeters aluminum.
70 kVp	1.6 millimeters aluminum.
90 kVp	2.6 millimeters aluminum.
100 kVp	2.8 millimeters aluminum.
110 kVp	3.0 millimeters aluminum.
120 kVp	3.3 millimeters aluminum.

(c) *Standard—termination of exposure.* A device is provided to terminate the exposure after a preset time or exposure.

(d) *Standard—control panel.* The control panel provides a device (usually a milliammeter or a means for an audible signal to give positive indication of the production of X-rays whenever the X-ray tube is energized. The control panel includes appropriate indicators (labelled control settings and/or meters) which show the physical factors (such as kVp, mA, exposure time or whether timing is automatic) used for the exposure.

(e) *Standard—exposure control switch.* The exposure control switch is of the dead-man type and is so arranged that the operator can stand at least 6 feet from the patient and well away from the useful beam.

(f) *Standard—protection against electrical hazards.* Only shockproof equipment is used. All electrical equipment is grounded.

(g) *Standard—mechanical supporting or restraining devices.* Mechanical supporting or restraining devices are provided so that such devices can be used when a patient must be held in position for radiography.

(h) *Standard—protective gloves and aprons.* Protective gloves and aprons are provided so that when the patient must be held by an individual, that individual is protected with these shielding devices.

(i) *Standard—restriction of the useful beam.* Diaphragms, cones, or adjustable collimators are used to restrict the useful beam to the area of clinical interest.

(j) *Standard—personnel monitoring.* A device which can be worn to monitor radiation exposure (e.g., a film badge) is provided to each individual who operates portable X-ray equipment. The device is evaluated for radiation exposure to the operator at least monthly and appropriate records are maintained by the supplier of portable X-ray services of radiation exposure measured by such a device for each individual.

(k) *Standard—personnel and public protection.* No individual occupationally exposed to radiation is permitted to hold patients during exposures except during emergencies, nor is any other individual regularly used for this service. Care is taken to assure that pregnant women do not assist in portable X-ray examinations.

[34 FR 388, Jan. 10, 1969. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, Jan. 9, 1995; 60 FR 45086, Aug. 30, 1995]

§ 486.110 Condition for coverage: Inspection of equipment.

Inspections of all X-ray equipment and shielding are made by qualified individuals at intervals not greater than every 24 months.

(a) *Standard—qualified inspectors.* Inspections are made at least every 24 months by a radiation health specialist who is on the staff of or approved by an appropriate State or local government agency.

(b) *Standard—records of inspection and scope of inspection.* The supplier maintains records of current inspections which include the extent to which equipment and shielding are in compliance with the safety standards outlined in § 486.108.

[34 FR 388, Jan. 10, 1969. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, Jan. 9, 1995; 60 FR 45086, Aug. 30, 1995; 60 FR 50447, Sept. 29, 1995]

Subpart D—Conditions for Coverage: Outpatient Physical Therapy Services Furnished by Physical Therapists in Independent Practice

§ 486.150 Condition for coverage: General requirements.

In order to be covered under Medicare as a supplier of outpatient physical therapy services, a physical therapist in independent practice must meet the following requirements:

(a) Be licensed in the State in which he or she practices.

(b) Meet one of the personnel qualifications specified in § 485.705(b).

(c) Furnish services under the circumstances described in § 410.60 of this chapter.

(d) Meet the requirements of this subpart.

[60 FR 2329, Jan. 9, 1995]

§ 486.151 Condition for coverage: Supervision.

The services are furnished by or under the direct supervision of a qualified physical therapist in independent practice.

[60 FR 2329, Jan. 9, 1995]

§ 486.153 Condition for coverage: Compliance with Federal, State, and local laws.

The physical therapist in independent practice and staff, if any, are in compliance with all applicable Federal, State, and local laws and regulations.

(a) *Standard: Licensure of facility.* In any State in which State or applicable local law provides for the licensing of the facility of a physical therapist, such facility is:

(1) Licensed pursuant to such law; or

(2) If not subject to licensure, is approved (by the agency of such State or locality responsible for licensing) as meeting the standards established for such licensing.

(b) *Standard: Licensure or registration of personnel.* The physical therapist in independent practice and staff, if any, are licensed or registered in accordance with applicable laws.

[41 FR 20865, May 21, 1976, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated and amended at 60 FR 2326, 2329, Jan. 9, 1995]

§ 486.155 Condition for coverage: Plan of care.

For each patient, a written plan of care is established and periodically reviewed by the individual who established it.

(a) *Standard: Medical history and prior treatment.* The physical therapist obtains the following information before or at the time of initiation of treatment:

(1) The patient's significant past history.

(2) Diagnosis(es), if established.

(3) Physician's orders, if any.

(4) Rehabilitation goals and potential for their achievement.

(5) Contraindications, if any.

(6) The extent to which the patient is aware of the diagnosis(es) and prognosis.

(7) If appropriate, the summary of treatment provided and results achieved during previous periods of physical therapy services or institutionalization.

(b) *Standard: Plan of care.* (1) For each patient there is a written plan of care that is established by the physician or by the physical therapist who furnishes the services.

(2) The plan indicates anticipated goals and specifies for physical therapy services the—

(i) Type;

(ii) Amount;

(iii) Frequency; and

(iv) Duration.

(3) The plan of care and results of treatment are reviewed by the physician or by the therapist at least as often as the patient's condition requires, and the indicated action is taken.

(4) Changes in the plan of care are noted in the clinical record. If the patient has an attending physician, the therapist who furnishes the services promptly notifies him or her of any change in the patient's condition or in the plan of care. (For Medicare patients, the plan must be reviewed by a physician in accordance with § 410.61(e).)

[54 FR 38679, Sept. 20, 1989. Redesignated and amended at 60 FR 2326, 2329, Jan. 9, 1995]

§ 486.157 Condition for coverage: Physical therapy services.

The physical therapist in independent practice provides an adequate program of physical therapy services and has the facilities and equipment necessary to carry out the services offered.

(a) *Standard: Adequate program.* The physical therapist will be considered to have an adequate physical therapy program when services can be provided, utilizing therapeutic exercise and the modalities of heat, cold, water, and electricity; patient evaluations are conducted; and tests and measurements of strength, balance, endurance, range of motion, and activities of daily living are administered.

(b) *Standard: Supervision of physical therapy services.* Physical therapy services are provided by, or under the supervision of, a qualified physical therapist.

[41 FR 20865, May 21, 1976, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated and amended at 60 FR 2326, 2329, Jan. 9, 1995]

§ 486.159 Condition for coverage: Coordination of services with other organizations, agencies, or individuals.

The physical therapist coordinates her physical therapy services with the health and medical services the patient receives from organizations or agencies or other individual practitioners through exchange of information that meets the following standard:

If a patient is receiving or has recently received, from other sources, services related to the physical therapy program, the physical therapist exchanges pertinent documented information with those other sources—

(a) On a regular basis;

(b) Subject to the requirements for protection of the confidentiality of medical records, as set forth in § 485.721 of this chapter; and

(c) With the aim of ensuring that the services effectively complement one another.

[60 FR 2329, Jan. 9, 1995]

§ 486.161 Condition for coverage: Clinical records.

The physical therapist in independent practice maintains clinical records on all patients in accordance with accepted professional standards and practices. The clinical records are completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information.

(a) *Standard: Protection of clinical record information.* Clinical-record information is recognized as confidential and is safeguarded against loss, destruction, or unauthorized use. Written procedures govern use and removal of records and include conditions for release of information. A patient's written consent is required for release of information not authorized by law.

(b) *Standard: Content.* The clinical record contains sufficient information to identify the patient clearly, to justify the diagnosis(es) and treatment, and to document the results accurately. All clinical records contain the following general categories of data:

(1) Documented evidence of the assessment of the needs of the patient, of an appropriate plan of care, and of the care and services provided,

(2) Identification data and consent forms,

(3) Medical history,

(4) Report of physical examination(s), if any,

(5) Observations and progress notes,

(6) Reports of treatments and clinical findings, and

(7) Discharge summary including final diagnosis(es) and prognosis.

(c) *Standard: Completion of records and centralization of reports.* Current clinical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's clinical record.

(d) *Standard: Retention and preservation.* Clinical records are retained for a period of time not less than:

(1) That determined by the respective State statute or the statute of limitations in the State, or

(2) In the absence of a State statute: (i) 5 years after the date of discharge or, (ii) in the case of a minor, 3 years after the patient becomes of age under State law, or 5 years after the date of discharge, whichever is longer.

(e) *Standard: Indexes.* Clinical records are indexed at least according to name of patient to facilitate acquisition of statistical clinical information and retrieval of records for administrative action.

[41 FR 20865, May 21, 1976, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated and amended at 60 FR 2326, 2329, Jan. 9, 1995]

§ 486.163 Condition for coverage—physical environment.

The physical environment of the office or facility of the physical therapist in independent practice affords a functional, sanitary, safe, and comfortable surrounding for patients, personnel, and the public.

(a) *Standard: Building construction.* The construction of the building housing the physical therapy office meets all applicable State and local building, fire, and safety codes.

(b) *Standard: Maintenance of the physical therapy office and equipment.* There is a written preventive-maintenance program to ensure that equipment is operative and that the physical therapy office is clean and orderly. All essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition, and is properly calibrated.

(c) *Standard: Other environmental considerations.* The building housing the physical therapy office is accessible to, and functional for, patients, personnel, and the public. Written effective procedures in aseptic techniques are followed by all personnel and the procedures are reviewed annually, and when necessary, revised.

(d) The physical therapist is alert to the possibility of fire and other nonmedical emergencies and has written plans that include—

(1) The means for leaving the office and the building safely, demonstrated, for example, by fire exit signs; and

(2) Other provisions necessary to ensure the safety of patients.

[41 FR 20865, May 21, 1976, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated and amended at 60 FR 2326, 2329, Jan. 9, 1995]

Subparts E-F—[Reserved]

Subpart G—Conditions for Coverage: Organ Procurement Organizations

SOURCE: 53 FR 6549, Mar. 1, 1988, unless otherwise noted. Redesignated at 60 FR 50447, Sept. 29, 1995.

§ 486.301 Basis and scope.

(a) *Statutory Basis.* (1) Section 1138(b) of the Act sets forth the requirements that an organ procurement organization must meet to have its organ procurement services to hospitals covered under Medicare and Medicaid. These include certification as a ''qualified'' organ procurement organization (OPO) and designation as the OPO for a particular service area.

(2) Section 371(b) of the PHS Act sets forth the requirements for certification and the functions that a qualified OPO is expected to perform.

(b) *Scope.* This subpart sets forth—

(1) The conditions and requirements that an OPO must meet;

(2) The procedures for certification and designation of OPOs; and

(3) The terms of the agreement with HCFA, and the basis for, and the effect of, termination of the agreement.

[61 FR 19743, May 2, 1996]

§ 486.302 Definitions.

As used in this subpart, the following definitions apply:

Certification or *recertification* means a HCFA determination that an entity meets the standards for a *qualified OPO* at § 486.304 of this subpart and is eligible for designation if it meets the additional conditions for designation at §§ 486.306 and 486.308. No payment ensues from certification alone.

Designation or *redesignation* means HCFA approval of an OPO for Medicare and Medicaid payment purposes under section 1138(b)(1)(F) of the Act. The terms are used interchangeably except when otherwise specifically indicated.

Entire standard metropolitan statistical area means a metropolitan statistical area, a consolidated metropolitan statistical area, or a primary statistical area listed in the State and Metropolitan Area Data Book published by the U.S. Bureau of the Census.

Open area means a service area for which HCFA has notified the public that it is accepting applications for designation.

Organ means a human kidney, liver, heart, lung, or pancreas.

Organ procurement organization means an organization that performs or coordinates the performance of retrieving, preserving and transporting organs and maintains a system of locating prospective recipients for available organs.

Potential donor means a person who dies in circumstances (causes and conditions of death, and age at death) that are generally acceptable for donation of at least one solid organ if the donor can be identified timely and permission for donation can be obtained.

Service area means a geographical area of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs and that either includes an entire standard metropolitan statistical area or does not include any part of such an area and that meets the standards of this subpart.

Transplant center means a hospital certified by Medicare to furnish directly, for a specific organ(s), transplant and other medical and surgical specialty services required for the care of transplant patients.

[53 FR 6549, Mar. 1, 1988, as amended at 59 FR 46514, Sept. 8, 1994. Redesignated and amended at 60 FR 50447, 50448, Sept. 29, 1995]

§ 486.304 General requirements.

(a) *Designation—a condition for payment.* Payment may be made under the Medicare and Medicaid programs for organ procurement costs attributable to payments made by an OPO only if the organization has been designated by the Secretary as an OPO, payment to which may be treated as organ procurement costs for reimbursement of hospitals under Medicare and Medicaid.

(b) *Requirements for designated status.* To be the designated OPO for a service area, an entity must do the following:

(1) Submit to HCFA a written application for designation, using the application form prescribed by HCFA.

(2) Be certified as a qualified OPO.

(3) Participate in the Organ Procurement and Transplantation Network as specified in § 486.308.

(4) Enter into an agreement with HCFA that meets the requirements set forth in paragraph (c) of this section.

(5) Upon its initial designation, meet the requirements at § 486.310(a)(3) or § 486.310(b)(4), as appropriate, concerning working relationships with hospitals or transplant centers. During the initial designation period, the OPO is not required to demonstrate compliance with §§ 486.310(a)(1) and (a)(2) or § 486.310(b)(1), which set forth performance standards for OPOs.

(6) To be redesignated after an initial designation period, comply with all the requirements of this subpart, including those at § 486.310, which set forth performance standards for OPOs.

(7) Obtain HCFA approval before entering into any change of ownership, merger, consolidation, or change in its service area (see § 486.318, which sets forth requirements concerning approval for changes in ownership and

service area). Failure to do so could result in termination.

(8) Enter into a working relationship with any hospitals, including transplant centers, in the OPO's service area that request a working relationship.

(c) *Agreement with HCFA.* An OPO must enter into an agreement with HCFA. The agreement is effective upon submission by the OPO and acceptance by HCFA, but may be terminated by either party. If an OPO agreement is terminated, payment for organ procurement services attributable to that OPO will not be made for services furnished on or after the effective date of termination. In the agreement, the OPO must agree to do the following:

(1) Maintain compliance with the requirements of titles XVIII and XIX of the Act, section 1138 of the Act, and applicable regulations, including the conditions set forth in this subpart, and the regulations of the OPTN approved and issued by the Secretary, and to report promptly to the Secretary any failure to do so.

(2) File a cost report in accordance with § 413.24(f) of this chapter within 3 months after the end of each fiscal year.

(3) Permit HCFA to designate an intermediary to determine the interim payment rate payable to the transplant hospitals for services provided by the OPO and to make a determination of reasonable cost based on the cost report it files.

(4) Provide budget or cost projection information as may be required to establish an initial interim payment rate.

(5) Pay to HCFA amounts that have been paid by HCFA to transplant hospitals as Medicare payment for organ recovery fees and that are determined to be in excess of the reasonable cost of the services provided by the OPO.

(6) Not charge an individual for items or services for which that individual is entitled to have payment made under the Medicare program.

(7) Maintain and make available to HCFA, the Comptroller General, or their designees data that show the number of organs procured and transplanted.

(8) Maintain data in a format that can be readily continued by a successor OPO and turn over to HCFA copies of all records, data, and software necessary to ensure uninterrupted service by a successor OPO that may be designated for all or part of its service area. Records and data subject to this requirement include records on individual donors (including identifying data and data on organs retrieved), records on transplant candidates (including identifying data and data on immune system and other medical indications), and procedural manuals and other materials used in conducting OPO operations. Donor records must include at least information identifying the donor (for example, name, address, date of birth, social security number), the organs and tissues (when applicable) retrieved, date of the organ retrieval, and test results.

(d) *When OPOs may apply for designation.* Entities may apply for designation whenever a service area becomes an open area.

(e) *Designation periods*—(1) *General.* An OPO is normally designated for 2 years. A designation period may not exceed 2 years but may be shorter.

(2) *Redesignation.* Redesignation must occur at least every 2 years and be completed before the end of an existing designation period.

(3) *Interim designation.* HCFA may designate an organization for an interim designation period if the period is needed in order for HCFA to make a final designation determination.

(i) The interim designee may be either the OPO previously designated for the service area or another organization.

(ii) The interim designation period does not exceed 180 days after the normal designation period has expired.

(iii) The interim designee must meet all requirements of section 371(b) of the Public Health Service Act (42 U.S.C. 273(b)) regarding qualified OPOs and must not be out of compliance with the requirements of section 1138(b)(1) (B) through (E) of the Act regarding requirements for payment of organ procurement costs under title XVIII or title XIX of the Act.

[53 FR 6549, Mar. 1, 1988, as amended at 59 FR 46514, Sept. 8, 1994 Redesignated and amended at 60 FR 50447, 50448, Sept. 29, 1995; 60 FR 53877, Oct. 18, 1995; 61 FR 19743, May 2, 1996]

§ 486.306 Qualifications for designation as an OPO.

To be designated as the OPO for a service area, an organization must, at the time of application and throughout the period of its designation, meet the following requirements:

(a) Be a nonprofit entity that is exempt from Federal income taxation under section 501 of the Internal Revenue Code of 1986.

(b) Have accounting and other fiscal procedures necessary to assure the fiscal stability of the organization, including procedures to obtain payment for kidneys and non-renal organs provided to transplant centers.

(c) Have an agreement with the Secretary to be reimbursed under Medicare for the procurement of covered organs.

(d) Document that it has a defined service area that meets the requirements of § 486.307.

(e) Have a director and such other staff, including an organ donation coordinator and an organ procurement specialist, necessary to obtain organs effectively from donors in its service area.

(f) Have a board of directors or an advisory board that has the authority to recommend policies relating to the donation, procurement, and distribution of organs. While an OPO may have more than one board, the members specified in paragraphs (f)(1) through (f)(5) of this section must be members of a single board. The board of directors or advisory board must be composed of the following:

(1) Members who represent hospital administrators, tissue banks, voluntary health associations in its service area and either intensive care or emergency room personnel.

(2) Members who represent the public residing in that area.

(3) A physician with knowledge, experience, or skill in the field of human histocompatibility, or an individual with a doctorate degree in a biological science and with knowledge, experience, or skills in the field of human histocompatibility.

(4) A neurosurgeon or another physician with knowledge or skills in the field of neurology.

(5) A transplant surgeon from each transplant center in its service area with which the OPO has arrangements to coordinate its activities.

(g) To identify potential organ donors, have documented evidence that—

(1) It has a working relationship with at least 75 percent of the hospitals that participate in the Medicare and Medicaid programs in its service area and that have an operating room and the equipment and personnel for retrieving organs; and

(2) It conducts systematic efforts intended to acquire all usable organs from potential donors.

(h) Arrange for the appropriate tissue typing of donated organs.

(i) Have a system to equitably allocate donated organs among transplant patients that is consistent with—

(1) ''Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs'' issued by the Centers for Disease Control and Prevention (CDC) that are appended to this subpart; and

(2) Rules of the Organ Procurement and Transplantation Network (OPTN), see § 486.308.

(j) Provide or arrange for the transportation of donated organs to transplant centers.

(k) Have arrangements to coordinate its activities with transplant centers in the area.

(l) Have arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage and distribution of tissues as may be appropriate to assure that all usable tissues are obtained from potential donors.

(m) Maintain and make available upon request of the Secretary, the Comptroller General, or their designees data that relate to the performance standards.

(n) Maintain data in a format that can be readily used by a successor OPO and agree to turn over to the Secretary copies of all records and data necessary to assure uninterrupted service by a successor OPO newly designated by HCFA.

(o) Have a procedure for ensuring the confidentiality of patient records. Information from or copies of records

may be released only to authorized individuals and the OPO must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records may be released by the OPO only in accordance with Federal or State laws, court orders, or subpoenas.

(p) Conduct and participate in professional education concerning organ procurement.

(q) Ensure that appropriate donor screening and infection tests, consistent with OPTN standards and the CDC guidelines that are appended to this subpart, are performed by a laboratory that is certified in the appropriate specialty or subspecialty of service in accordance with part 493 of this chapter, including tests to prevent the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome.

(r) Assist hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors.

(s) Ensure that donors are tested for human immunodeficiency viral markers consistent with OPTN rules and the CDC guidelines appended to this subpart for solid organ donation.

(t) Submit accurate data to HCFA within 15 days following the end of a calendar year (unless otherwise notified) giving information on the following:

(1) Population of designated service area based on the most recent U.S. Bureau of the Census data.

(2) Number of actual donors.

(3) Number of kidneys procured.

(4) Number of kidneys transplanted.

(5) Number of extrarenal organs by type procured.

(6) Number of extrarenal organs by type transplanted.

[53 FR 6550, March 1, 1988; 53 FR 9172, March 21, 1988; 53 FR 18987, May 26, 1988; 57 FR 7137, Feb. 28, 1992; 59 FR 46515, Sept. 8, 1994. Redesignated and amended at 60 FR 50447, 50448, Sept. 29, 1995; 61 FR 19743, May 2, 1996]

§ 486.307 OPO service area size designation and documentation requirements.

(a) *General documentation requirement.* An OPO must make available to HCFA documentation verifying that the OPO meets the requirements of paragraphs (b) through (d) of this section at the time of application and throughout the period of its designation.

(b) *Boundary designation.* The defined service area either includes an entire Metropolitan Statistical Area or a New England County Metropolitan Area as specified by the Director of the Office of Management and Budget or does not include any part of such an area.

(c) *Service area location and characteristics.* An OPO must precisely define and document a proposed service area's location through the following information:

(1) The names of counties (or parishes in Louisiana) served or, if the service area includes an entire State, the name of the State.

(2) Geographic boundaries of the service area for which U.S. population statistics are available.

(3) Total population in service area.

(4) The number of and the names of acute care hospitals in the service area with an operating room and the equipment and personnel to retrieve organs.

(d) *Sufficient size requirements.* (1) Before January 1, 1996, an OPO must demonstrate that it can procure organs from at least 50 potential donors per calendar year or that its service area comprises an entire State.

(2) Beginning January 1, 1996, an OPO must meet at least one of the following requirements:

(i) Its service area must include an entire State or official U.S. territory.

(ii) It must either procure organs from an average of at least 24 donors per calendar year in the 2 years before the year of redesignation or request and be granted an exception to this requirement under paragraph (d)(3) or (d)(4) of this section.

(iii) In the case of an OPO operating exclusively in a noncontiguous U.S. State, a U.S. territory, or a U.S. commonwealth, such as Hawaii or Puerto Rico, it must procure organs at the rate of 50 percent of the national average of all OPOs for kidney procurement per million population and for kidney transplantation per million population.

(iv) If it is an entity that has not been previously designated as an OPO,

it must demonstrate that it can procure organs from at least 50 potential donors per calendar year.

(3) HCFA may grant an OPO an exception to paragraph (d)(2)(ii) of this section if the OPO can demonstrate that—

(i) It failed to meet the requirement because of unusual circumstances beyond its control;

(ii) It has historically maintained a service area of sufficient size to meet the criterion in paragraph (d)(2)(ii) of this section; and

(iii) It has a specific plan to meet the size criterion in paragraph (d)(2)(ii) of this section in the future.

(4) During the 1996 redesignation process only, HCFA may grant an exception to paragraph (d)(2)(ii) of this section to an OPO that can demonstrate that—

(i) It meets the performance criteria in § 486.310(b); and

(ii) It has a specific plan to meet the service area size criterion in paragraph (d)(2)(ii) of this section by the 1998 redesignation period.

[61 FR 19744, May 2, 1996]

§ 486.308 Condition: Participation in organ procurement and transplantation network.

In order to be designated as the OPO for its service area, and to continue to be the designated OPO once designated, an OPO must be a member of, have a written agreement with, and abide by the rules of the OPTN established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274). 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. No OPO is considered to be out of compliance with section 1138(b)(1)(D) of the Act or this section unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the entity from the OPTN and also has notified the entity in writing.

[59 FR 46516, Sept. 8, 1994. Redesignated and amended at 60 FR 50447, 50448, Sept. 29, 1995]

§ 486.310 Condition: Adherence to performance standards.

(a) *Standards before January 1, 1996.* Before January 1, 1996, OPOs must meet the following performance standards:

(1) Each OPO must procure within its service area a minimum ratio of 23 cadaveric kidneys per million population of its service area for each 12-month period surveyed.

(2) Each OPO must provide a minimum ratio of cadaveric kidneys procured in its service area and transplanted (either locally or exported and transplanted) of 19 cadaveric kidneys per million population of its service area for each 12-month period surveyed.

(b) *Standards beginning on January 1, 1996.* Except as specified in paragraph (c) of this section, each OPO must achieve at least 75 percent of the national mean for four of the following five performance categories, averaged over the 2 calendar years before the year of redesignation:

(1) Number of actual donors per million population.

(2) Number of kidneys recovered per million population.

(3) Number of extrarenal organs recovered per million population.

(4) Number of kidneys transplanted per million population.

(5) Number of extrarenal organs transplanted per million population.

(c) *Exceptions and exemptions*—(1) *Exception based on location.* OPOs operating exclusively in a noncontiguous U.S. State, a U.S. territory, or a U.S. commonwealth, such as Hawaii or Puerto Rico, may be granted an exception from the performance standards of paragraph (b) of this section because of special geographically related characteristics, such as difficulty in transporting organs to the mainland, that impede satisfaction of the national rate of organ procurement. They must meet a standard of 50 percent of the national average of all OPOs for kidneys recovered and transplanted per million population.

(2) *Exception because of lack of competition for a service area.* HCFA may continue to designate an OPO that does not meet the standards under paragraph (b) of this section for a service

area if no OPO that meets the performance and qualification requirements is willing to accept responsibility for the service area and if the designated OPO submits an acceptable corrective action plan in accordance with paragraph (d) of this section.

(3) *Exception for 1996 transition period.* During the 1996 designation period only, HCFA may continue to designate for a service area an OPO that does not meet the standards under paragraph (b) of this section if the OPO:

(i) Meets three of the criteria in paragraphs (b)(1) through (b)(5) of this section; and

(ii) Submits an acceptable corrective action plan in accordance with paragraph (d) of this section.

(d) *Corrective action plans and corrected information*—(1) *Corrective action plans.* (i) If a designated OPO does not meet the standards of paragraph (a) of this section, it may submit to the appropriate HCFA regional office a corrective action plan explaining why it failed to meet them and specifying the actions it will take to ensure it meets those standards in the future.

(ii) HCFA will not accept corrective action plans from an OPO for failure to meet the standards specified in paragraph (b) of this section unless the OPO continues to be designated under paragraph (c)(2) or (c)(3) of this section.

(2) *Corrected information.* An OPO may request correction of the information required by § 486.306(e) from HCFA throughout the two-year designation period. HCFA will evaluate the OPO's request and may seek input from other sources, such as hospital personnel, neighboring OPOs, the OPTN contractor, and the Census Bureau as necessary to verify the OPO's information before making the changes requested by the OPO. In addition, HCFA will notify an OPO if it does not meet the performance standards based on the information reported. Any OPO so notified may provide corrected information for consideration within 30 days of receipt of a notice of failure to meet the standards.

[59 FR 46516, Sept. 8, 1994. Redesignated and amended at 60 FR 50447, 50448, Sept. 29, 1995; 61 FR 19744, May 2, 1996]

§ 486.314 Effect of failure to meet requirements.

Failure to continue to meet any of the requirements in §§ 486.306 and 486.308 or to meet the performance standards in § 486.310 may result in termination of the OPO's agreement with HCFA.

[59 FR 46517, Sept. 8, 1994. Redesignated and amended at 60 FR 50447, 50448, Sept. 29, 1995; 61 FR 19745, May 2, 1996]

§ 486.316 Designation of one OPO for each service area.

(a) HCFA designates only one OPO per service area. Applications for designation are accepted only during a period when the service area is an open area. A service area is open for competition once the existing designation period has expired, when the existing designated status of the OPO for that service area has been terminated, or when no OPO has been designated for the area. HCFA may also declare the service area open in the event an OPO ceases to operate or HCFA has reasonable ground for anticipating it will cease to operate. In cases of urgent need (such as evidence of medically or ethically unsound practices), HCFA may terminate its agreement with an OPO immediately. The service area remains open until an OPO is designated for it. If more than one organization applies and substantially meets the requirements of § 486.306 in a given service area, HCFA considers other factors in reaching a decision concerning which organization to designate. These factors follow:

(1) Prior performance, including the previous year's experience in terms of the number of organs retrieved and wasted and the average cost per organ;

(2) Actual number of donors compared to the number of potential donors;

(3) The nature of relationships and degree of involvement with hospitals in the organization's service area;

(4) Bed capacity associated with the hospitals with which the organizations have a working relationship;

(5) Willingness and ability to place organs within the service area; and

(6) Proximity of the organization to the donor hospitals.

(b) An organization that applies to HCFA to be the designated OPO for its service area and that is not designated may appeal its nondesignation under part 498 of this chapter.

(c) After January 1, 1996, a hospital must enter into an agreement only with the OPO designated to serve the area in which the hospital is located unless HCFA has granted the hospital a waiver under paragraphs (d) through (g) of this section to be serviced by another OPO.

(d) If HCFA changes the OPO designated for an area, hospitals located in that area must enter into agreements with the newly designated OPO or submit a request for a waiver in accordance with paragraph (e) of this section within 30 days of notice of the change in designation.

(e) A hospital may request and HCFA may grant a waiver permitting the hospital to have an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located. To qualify for a waiver, the hospital must submit data to HCFA establishing that—

(1) The waiver is expected to increase organ donations; and

(2) The waiver will ensure equitable treatment of patients referred for transplants within the service area served by the hospital's designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement.

(f) In making a determination on waiver requests, HCFA considers:

(1) Cost effectiveness;

(2) Improvements in quality;

(3) Changes in a hospital's designated OPO due to changes in the metropolitan service area designations, if applicable; and

(4) The length and continuity of a hospital's relationship with an OPO other than the hospital's designated OPO.

(g) A hospital may continue to operate under its existing agreement with an out-of-area OPO while HCFA is processing the waiver request. If a waiver request is denied, a hospital must enter into an agreement with the designated OPO within 30 days of notification of the final determination.

[59 FR 46517, Sept. 8, 1994. Redesignated and amended at 60 FR 50447, 50448, Sept. 29, 1995; 61 FR 19745, May 2, 1996]

§ 486.318 Changes in ownership or service area.

(a) *OPO requirements.* (1) A designated OPO considering a change in ownership or in its service area must notify HCFA before putting it into effect. This notification is required to ensure that the entity, as changed, will continue to satisfy Medicare and Medicaid requirements. A change in ownership takes place if there is the merger of one entity into another or the consolidation of one entity with another.

(2) A designated OPO considering a change in its service area must obtain prior HCFA approval. In the case of a service area change that results from a change of ownership due to merger or consolidation, the entities must submit anew the information required in an application for designation, or other written documentation HCFA determines to be necessary for designation.

(b) *HCFA requirements.* (1) If HCFA finds that the entity has changed to such an extent that it no longer satisfies the prerequisites for OPO designation, HCFA may terminate the OPO's agreement and declare the OPO's service area to be an open area.

(2) If HCFA finds that the changed entity continues to satisfy the prerequisites for OPO designation, the period of designation of the changed entity is the remaining designation term of the OPO that was reorganized. If more than one designated OPO is involved in the reorganization, the remaining designation term is ordinarily the longest of the remaining periods. HCFA may determine, however, that a shorter period applies if it decides that a shorter period is in the best interest of the Medicare and Medicaid programs. The performance standards of § 486.310 apply at the end of this remaining period.

[59 FR 46517, Sept. 8, 1994. Redesignated and amended at 60 FR 50447, 50448, Sept. 29, 1995]

§ 486.325 Terminations of agreement with HCFA.

(a) *Types*—(1) *Voluntary termination*. If an OPO wishes to terminate its agreement, it must send written notice of its intention with the proposed effective date to HCFA. HCFA may approve the proposed date, set a different date no later than 6 months after the proposed effective date, or set a date less than 6 months after the proposed date if it determines that it would not disrupt services to the service area or otherwise interfere with the effective and efficient administration of the Medicare and Medicaid programs. If HCFA determines that a designated OPO has ceased to furnish organ procurement services to its service area, the cessation of services is deemed to constitute a voluntary termination by the OPO, effective on a date determined by HCFA.

(2) *Involuntary termination*. HCFA may terminate an agreement if it finds that an OPO no longer meets the conditions for coverage in this subpart, or is not in substantial compliance with any other applicable Federal regulations or provisions of titles XI, XVIII, or title XIX of the Act. HCFA may also terminate an agreement immediately in cases of urgent need, such as the discovery of unsound medical practices.

(b) *Notice to OPO*. HCFA gives notice of termination to an OPO at least 90 days before the effective date stated in the notice.

(c) *Appeal right*. The OPO may appeal the termination in accordance with the provisions set forth in part 498, which sets forth appeals procedures for determinations that affect participation in the Medicare and Medicaid programs.

(d) *Effects of termination*. When an OPO agreement is terminated—

(1) Medicare and Medicaid payments may not be made for organ procurement services the OPO furnishes on or after the effective date of termination; and

(2) HCFA will accept applications from any entity to be the designated OPO for that area.

(e) *Public notice*. In the case of voluntary termination, the OPO must give prompt public notice of the date of termination, and such information regarding the effect of that termination as HCFA may require, through publication in local newspapers in the service area. In the case of involuntary termination, HCFA gives notice of the date of termination.

(f) *Reinstatement*. HCFA may, at its discretion, designate an OPO whose agreement was previously terminated if HCFA finds that the cause for termination has been removed, is satisfied that it is not likely to recur, has not designated another OPO for the service area, and finds that the OPO meets all the necessary requirements for designation.

[59 FR 46517, Sept. 8, 1994. Redesignated and amended at 60 FR 50447, 50448, Sept. 29, 1995; 61 FR 19745, May 2, 1996]

APPENDIX A TO SUBPART G OF PART 486

Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs

Summary

Although previous recommendations for preventing transmission of human immunodeficiency virus (HIV) through transplantation of human tissue and organs have markedly reduced the risk for this type of transmission, a case of HIV transmission from a screened, antibody-negative donor to several recipients raised questions about the need for additional federal oversight of transplantation of organs and tissues. A working group formed by the Public Health Service (PHS) in 1991 to address these issues concluded that further recommendations should be made to reduce the already low risk of HIV transmission by transplantation of organs and tissues. In revising these recommendations, the PHS sought assistance from public and private health professionals and representatives of transplant, public health, and other organizations. The revised guidelines address issues such as donor screening, testing, and exclusionary criteria; quarantine of tissue from living donors; inactivation or elimination of infectious organisms in organs and tissues before transplantation; timely detection, reporting, and tracking of potentially infected tissues, organs, and recipients; and recall of stored tissues from donors found after donation to have been infected. Factors considered in the development of these guidelines include differences between the screening of living and cadaveric donors; time constraints due to organ/tissue viability that may preclude performing certain screening procedures; differences in the risk of HIV transmission from various organs and tissues; differences between systems for procuring and distributing organs and tissues; the effect of screening practices on the limited availability of organs and some tissues; and the benefit of the transplant to the recipient.

INTRODUCTION

Exclusion of prospective blood donors based on their acknowledged risk behaviors for human immunodeficiency virus (HIV) infection began in 1983 (*1*). In 1985, when tests for HIV antibody became available, screening prospective donors of blood, organs, and other tissues also began (*2,3*). Both measures have reduced markedly the transmission of HIV via these routes.

A 1991 investigation determined that several recipients had been infected with HIV by an organ/tissue donor who had tested negative for HIV antibody at the time of donation (*4*). This occurrence raised questions about the need for additional federal oversight of transplantation of organs and tissues. To address these questions, the Public Health Service (PHS) formed a working group comprising representatives from several federal agencies. The working group concluded that, although existing recommendations are largely sufficient, revisions should be made to reduce the already low risk of HIV transmission via transplantation of organs and tissues. Adequate federal

regulations, recommendations, and guidelines for blood and plasma are already established and are not addressed in this document.

Those developing guidelines for other organs and tissues should consider donor screening and testing; quarantine of tissue from living donors; inactivation or elimination of infectious organisms in organs and tissues before transplantation; timely detection, reporting, and tracking of potentially infected organs, tissues, and recipients; and recall of stored tissue from donors found after donation to have been infected.

These guidelines apply largely to donation and transplantation of organs and solid tissues. Although they also apply generally to donation of human milk and semen, some modifications may be needed because donors of human milk and semen are living and often donate repeatedly. Additionally, donor milk should be pasteurized (a heating procedure that inactivates HIV) before dispensing. This document can serve as a general guide to facilities that bank breast milk or semen and should be followed where feasible.

In revising these recommendations for transplantation of organs and tissues, PHS sought assistance from public and private health professionals and representatives of transplant, public health, and other organizations (see pages iii-v). These guidelines do not supersede existing state laws but are to be implemented in accordance with existing statutes.

BACKGROUND

Epidemiology of HIV Infection in Recipients of Organs and Tissues

Most transmission of HIV to organ/tissue recipients occurred before 1985, before the implementation of donor screening. In addition to HIV transmission through blood and blood products, reports of HIV infection following transplantation have implicated the kidney, liver, heart, pancreas, bone, and possibly skin as sources of infection (*4*). HIV has also been transmitted from infected semen during artificial insemination (*5*). Several studies and case reports indicate that HIV can be transmitted through breast milk from HIV-infected women to their children (*6,7*); these investigations include several prospective studies indicating that breast-fed infants are at greater risk of acquiring HIV from their infected mothers than are bottle-fed infants (*8,9*).

Reports of transmission from screened, HIV-antibody–negative donors of organs or tissues have been rare. In one instance, hemodilution from multiple transfusions given to the organ/tissue donor before collection of the blood sample resulted in an HIV-antibody test result that was initially false negative (*10*). Serum samples taken on admission, before the transfusions, and 2 days after the transfusions later tested positive for antibody to HIV. In another instance, a kidney donor tested HIV-antibody negative 8 months before donation but seroconverted between the time of testing and donation (*11*). The donor was not retested at the time of donation. In a third instance, an organ from an HIV-infected donor was transplanted under emergency conditions before results of the HIV-antibody test were known (*12*).

A fourth case involved transmission from an organ/tissue donor whose HIV-antibody test was negative at the time of donation (*4*). Most likely, the donation occurred sometime between infection and antibody seroconversion, which, for most

infected persons, ranges from 4 weeks to 6 months (*13*). Six years after the donor's death and ensuing donation, HIV infection in the stored donor material was confirmed by virus culture and polymerase chain reaction (PCR) of stored donor lymphocytes (*4*). Among the 41 recipients identified and tested, those who received the solid organs and unprocessed, fresh-frozen bone acquired HIV infection from the allografts (one recipient of a heart, two recipients of kidneys, one recipient of a liver, and three recipients of fresh-frozen bone). The recipients of other processed bone and relatively avascular soft tissue (fascia lata, tendons, ligaments, dura mater, and corneas) did not become HIV infected (*4*).

Current Use of Organ and Tissue Transplants

The number of transplants has grown considerably over the last several years, a phenomenon attributable to many factors, including the availability of improved immunosuppressant drugs. Approximately 66 Organ Procurement Organizations (OPOs) and 260 organ transplant centers are members of the Organ Procurement and Transplantation Network (OPTN). In 1990 these centers recovered approximately 15,000 organs (e.g., kidney, liver, heart, lung, and pancreas) from 4,500 donors.

OPOs and tissue banks also recovered tissues (other than the organs listed above) from an estimated 7,500–10,000 donors in 1990. These tissues were used in approximately 250,000–300,000 (mostly bone) allografts.

In 1990, member banks of the Eye Bank Association of America (EBAA) retrieved ocular tissue from more than 40,000 donors. These tissues are used for corneal transplantation and are also processed into epikeratophakia lenticules (EBAA Statistical Report, 1990).

More than 400 establishments either bank or commercially process one or more human tissues. Approximately 100 eye banks and 125 bone banks operate in the United States (although the number of hospitals that store bone for future transplantation is difficult to estimate). Also, several hospitals may retrieve and store bone from living donors. Seven human milk banks operating in the United States process donor breast milk.

The American Fertility Society is aware of approximately 100 semen banks in the United States. Slightly fewer than half of artificial inseminations performed in the United States involve unrelated-donor semen used to inseminate approximately 75,000 women per year. In addition to these 100 semen banks, an undetermined number of smaller banks are hospital based or located in the offices of individual physicians.

The National Heart, Lung, and Blood Institute (NHLBI) within the National Institutes of Health (NIH) is aware of 99 bone marrow transplant centers, of which 41 participate in programs involving bone marrow transplants from unrelated donors. Many additional facilities are equipped to obtain marrow from donors. About 2,200 bone marrow transplants involving allogeneic marrow took place in the United States in 1991. Of those, approximately 435 were provided by donors who were not related to the recipients. Peripheral blood stem cells are being used for autologous transplantation and, in the future, may be useful for allogeneic use. Furthermore, cord blood stem cells are being used for both related- and unrelated-donor allogeneic transplantation.

Current Guidelines and Recommendations

Procedures for procurement and transplantation of organs and tissues are addressed by a) federal laws, regulations, and guidelines; b) state laws and regulations; and c) voluntary industry standards. Several federal agencies either directly or indirectly regulate procurement and transplantation of organs and tissues. These activities range from the publication of guidelines that address the transmission of communicable diseases through transplantation to regulatory requirements for registration and premarket product licensure or approval (blood and certain other tissue products).

The Health Resources and Services Administration (HRSA), through the United Network for Organ Sharing (UNOS), administers the contract for OPTN as required by Section 372 of the Public Health Service Act and as amended [42 USC 274]. The contract covers specified solid organs (kidney, liver, heart, lung, and pancreas) but does not cover corneas, eyes, or other tissues. Technically, all UNOS policies are voluntary; however, HRSA is currently developing regulations dealing with OPTN membership and operation.

Under a separate contract with HRSA, UNOS maintains a Scientific Registry for Transplant Recipients that includes information on all solid-organ transplant recipients (since October 1, 1987) from the date of transplantation until failure of the graft or death of the patient. In addition, HRSA informally conveys recommendations to organizations involved in procurement and transplantation of organs. Through OPTN and the Scientific Registry for Transplant Recipients, HRSA has the capacity to link organ donors and their recipients.

FDA regulates a limited number of specific tissues as either "biological products" or "medical devices." Examples of tissues include blood, dura mater, corneal lenticules, umbilical veins, nonautologous cultured skin, and heart valves. In addition, FDA has recently published regulations regarding behavioral screening and infectious-disease testing (HIV-1, HIV-2, hepatitis B virus, and hepatitis C virus) for donors of human tissue for transplantation (*14*). FDA also regulates certain agents and devices for processing bone marrow, although bone marrow transplants from unrelated donors are under the auspices of NHLBI.

NHLBI manages the federal contract for the National Marrow Donor Program. Two bone marrow donor registries currently exist: one independent registry and one registry managed through the NHLBI contractor. Each registry group has voluntary guidelines/standards that resemble blood-banking standards. Although federal regulations have not yet been promulgated, the current practice of bone marrow acquisition and transplantation includes procedures to reduce the risk of HIV transmission. NHLBI is preparing regulations that will set forth criteria, standards, and procedures for entities involved in bone marrow collection, processing, and transplantation. These entities include the National Marrow Donor Registry, individual donor centers, donor registries, marrow-collection centers, and marrow-transplant centers. The regulations will include donor-selection criteria to prevent the transmission of infectious diseases, including HIV infection.

Donor Screening

PHS has made recommendations for preventing HIV transmission through organ/tissue transplantation and artificial insemination (*1–3,15,16*). These

recommendations include screening for behaviors that are associated with acquisition of HIV infection, a physical examination for signs and symptoms related to HIV infection, and laboratory screening for antibody to HIV.

PHS has made no specific recommendations for donation and banking of human milk, although HIV-infected women in the United States are advised to avoid breast feeding their infants because of the risk of HIV transmission through breast milk (*17*). The Human Milk Banking Association of North America has issued guidelines for the establishment and operation of human milk banks (*18*). These guidelines state that all human milk donors should be screened according to the American Association of Blood Banks' standards for screening blood donors. All milk accepted for donation should be pasteurized unless the recipient's condition requires fresh-frozen milk, in which case the milk bank director should consult with the medical director and advisory board to approve the dispensing of microbiologically screened, fresh-frozen milk from suitable donors.

Since March 1985, the FDA has licensed a number of screening and supplemental tests for detection and confirmation of HIV antibody. All these tests are intended for use on either fresh or freezer-stored samples of serum or plasma. The FDA has not required manufacturers to submit data showing that HIV-1 antigen and antibody-detection kits produce accurate results when applied to postmortem blood samples. Postmortem blood samples are often hemolyzed, which may affect the specificity of screening assays for HIV antibody (*19,20*).

The screening tests include enzyme immunoassays (EIAs), several of which are also approved for testing blood spots dried onto a specific filter paper, which may provide a method for storing samples. Rapid screening assays for HIV antibody that use a latex-agglutination or EIA (microparticle-based) format have also been approved for screening serum, plasma, or whole blood. A licensed EIA for detecting antibodies to HIV-2 is also commercially available, as are "combination tests" that simultaneously detect antibodies to HIV-1 and HIV-2 (*21*). FDA has also licensed one manufacturer to make and distribute a test for detection of HIV-1 p24 antigen for patient diagnosis and prognosis of HIV infection but not for screening blood donors.

Western blot tests and an immunofluorescence assay for HIV-1 are approved for supplemental, more specific testing of serum, plasma, and whole-blood samples found reactive by HIV-1 antibody screening tests. No additional, more specific test is approved that confirms either antibodies to HIV-2 (*21*) or eluted, dried blood-spot results. The licensed p24-antigen test includes a neutralization procedure that is to be used for specific testing of samples with repeatedly reactive test results.

Federal regulations already require that all donations of blood, blood components, and plasma intended for further processing into injectable products ("source plasma") be screened with a licensed test that detects HIV antibody. Since June 1992, PHS has also required that all blood and plasma donations be screened for HIV-2 antibody.

PHS has not recommended the use of the licensed HIV-1 p24-antigen assay for screening donated blood or source plasma, nor has the kit been approved for use in donor screening. This position is based on findings from several studies indicating that a blood donor with a positive test for antigen and a negative test for antibody is rare (*22,23*). Such rarity is probably attributable to the effectiveness of the donor-qualification procedures, including donor education, voluntary exclusion, and

antibody testing that together operate to prevent donation by persons at increased risk for HIV infection.

Limited studies have been conducted to examine the use of the p24-antigen assay to screen organ/tissue donors (*19,20,24*). Among approximately 1,000 samples from HIV-1 antibody-negative donors, no donors had detectable HIV-1 p24 antigen.

Recipient Screening

Until recently, PHS had made no recommendations regarding routine testing of recipients of organs, tissues, semen, or donated human milk. However, in response to the July 18, 1991, report of the PHS Workgroup on Organ and Tissue Transplantation, HRSA asked UNOS to request that transplant centers implement an interim voluntary HIV-testing policy for organ recipients. HRSA has requested that recipients be tested for HIV-1 antibody immediately before transplantation and at 3, 6, and 12 months after transplantation. If HIV infection is diagnosed in an organ recipient, the results of the HIV test are reported by the transplant center to the Scientific Registry for Transplant Recipients and to the procuring OPO, in accordance with existing state laws. No comparable registry exists for recipients of tissues, semen, or donated human milk. However, the National Marrow Donor Program routinely tracks both donors and recipients of bone marrow for unrelated-donor transplants. This program reports no known seroconversions among either donors or recipients, although recipients are not routinely screened for HIV.

Routine testing of recipients after transplantation has several potential benefits. First, early identification of HIV infection in a recipient allows for early intervention before signs and symptoms develop. Both antiviral therapy to prevent progression to acquired immunodeficiency syndrome (AIDS) (*25*) and prophylactic therapy to prevent opportunistic infections (*26,27*) have been recommended for HIV-infected patients, based on CD4+ T-lymphocyte levels. Second, early identification of HIV infection in a transplant recipient allows for early intervention to prevent further transmission from the recipient to sex or needle-sharing partners and to future offspring (through vertical transmission from mother to infant). Third, early identification of HIV infection in a recipient potentially identifies an infectious donor. Should further investigation indicate that the donor is the source of the HIV infection in the recipient, other recipients of tissue from that same donor can be notified and stored tissue can be retrieved, preventing further transmission through transplantation.

Concern has been expressed that linking HIV infection in a transplant recipient to the transplantation may be difficult because many recipients may have also received blood or blood products or have other risk factors. However, identification of multiple HIV-infected recipients of tissue from the same donor strongly implicates the donor as the source of the HIV infection in the recipients. In addition, stored blood or lymphoid samples from the donor (when available) can be tested for the presence of virus to confirm the HIV-infection status of the donor (*4*).

Questions have been raised about whether transplant recipients who may be receiving immunosuppressive therapy to prevent rejection are capable of producing antibody against HIV if transmission occurs. Several reports now indicate that the HIV-antibody response is not delayed in transplant recipients receiving antirejection therapy, which primarily affects cellular immunity (*4*).

The additional costs of routine screening for HIV in recipients must be considered as well. The Institute of Medicine has estimated that laboratory costs are approximately $4 for a patient who tests negative and $35 for a patient who tests positive. (The latter cost includes the added expense of repeat EIAs and Western blot or other supplemental tests.) These costs may be underestimates, however. The time required for pretest and posttest counseling was estimated to be approximately 0.5–1.0 hour for an HIV-seronegative patient and 1.5–2.0 hours for an HIV-seropositive patient (*28*).

Inactivation of HIV in Tissues

Thorough donor screening is considered the most effective method for preventing HIV transmission through transplantation; however, the use of chemical or physical inactivating or sterilizing agents to reduce further the already low risk of transmission has been considered. If such agents are to be useful, they must either inactivate or eliminate the virus while maintaining the functional integrity of the tissue or organ.

No mechanism for inactivating virus in whole organs currently exists. However, several agents have been suggested as possible disinfectants for tissues such as bone fragments (*4*). Pasteurization has been shown to inactivate HIV in human milk without substantially compromising nutritional and immunologic characteristics (*29*).

Although some physical and chemical agents have been shown to reduce the likelihood of isolating virus from treated solid tissues, conclusive evidence that those processes render solid tissue completely safe yet structurally intact is lacking. In the recent case of an HIV-infected donor who was antibody negative (*4*), tissues that had been processed in a variety of ways did not transmit HIV. These tissues included a) lyophilized fascia lata, tendons, or ligaments; b) dura mater that was lyophilized and irradiated with 3.0–3.4 Mrad of gamma radiation through a cobalt-60 source; c) bone fragments that were treated with ethanol and lyophilized; and d) one sample of fresh-frozen long bone with the marrow elements evacuated (*4*). However, because most of these tissues were relatively avascular, it is unclear whether the absence of HIV transmission was due to processing, avascularity, or both.

General Considerations

In developing guidelines for preventing HIV transmission from organ/tissue donors to recipients, several factors were considered: a) differences between the screening of living, brain-dead, and cadaveric donors; b) time constraints due to organ/tissue viability that may preclude performing certain screening procedures; c) differences in the risk for HIV transmission from various organs and tissues; d) differences between systems in place for procuring and distributing organs and tissues; e) the effect of screening practices on the limited availability of organs and some tissues; and f) the benefit of the transplant to the recipient (i.e., some transplants are lifesaving, whereas others are life enhancing).

Living donors can be interviewed about potential high-risk behavior, whereas deceased donors cannot. In the case of brain-dead or cadaveric donors, family members and others may be unable to provide an accurate risk history. Therefore, exclusion of potentially infected brain-dead or cadaveric donors relies even more heavily on laboratory screening and physical examinations than on interviews regarding high-risk behavior.

Screening procedures that require more than 24 hours to complete may not be feasible for brain-dead or cadaveric donors of organs and certain tissues. Most tissues must be recovered and most organs must be recovered and transplanted shortly after cessation of circulatory function of the donor. Whereas some tissues can be stored for months, others must be transplanted within a few days after procurement. These time constraints may limit the ability to interview certain family members or significant life partners who are not nearby and may preclude the use of certain laboratory screening tests that cannot be performed within these time constraints.

The precise risk of HIV transmission from various tissues is not known, yet some organs and tissues clearly present a higher risk for HIV transmission than others (*4*). For example, studies indicate that the risk for transmission from an organ of an HIV-infected donor is nearly 100%. Fresh-frozen, unprocessed bone also appears to carry a high risk for transmission, particularly if marrow elements and adherent tissue are not removed. Relatively avascular solid tissue, some of which is also processed by using techniques that might inactivate HIV, appears to carry a lower risk for HIV transmission.

As noted earlier in these guidelines, there is considerable variability in the role of federal agencies regarding transplantation of organs and tissues and the procurement and distribution systems. Oversight for, existence of, and compliance with recommendations also vary between these systems. When organs and tissues are procured from a single donor, tracking systems must involve multiple distribution systems that may be difficult to link.

Donor-screening practices must also consider the already inadequate supply of most organs and tissues needed for transplantation. However, even though attempts should be made to ensure the highest level of safety, donor-screening practices should not unnecessarily exclude acceptable potential donors.

Those involved in developing guidelines should consider that some transplants are lifesaving (e.g., a heart transplant), whereas others are life enhancing. Some physicians may be willing to offer the patient a transplant of a lifesaving organ from a donor whose HIV risk status is questionable but would not use life-enhancing tissue from such a donor.

RECOMMENDATIONS

Donor Screening

1. All prospective living donors or next of kin or significant life partners accompanying brain-dead or cadaveric donors should be informed of the general nature of the donor-evaluation process, including a review of medical and behavioral history, physical examination, and blood tests to exclude infectious agents that might be transmitted by organ or tissue transplant.

2. Prospective living donors or next of kin or significant life partners accompanying brain-dead or cadaveric donors should be informed about modes of transmission and risk factors for HIV infection, emphasizing that HIV can be transmitted via transplanted organs and tissues. They should be told that a negative test for HIV antibody does not guarantee that the donor is free of HIV infection because of the

rare situation of donation after infection but before seroconversion. Therefore, organs and tissue must not be transplanted from persons who may have engaged in activities that placed them at increased risk for HIV infection. This information should be presented in simple language to ensure that the donor, next of kin, or significant life partner understands what is considered high-risk behavior and the importance of excluding persons who have engaged in this behavior. Persons soliciting the donation should not place undue pressure to donate on potential living donors and those persons providing permission for potential brain-dead or cadaveric donors who might otherwise decline to donate or give permission because of high-risk behavior.

3. To ascertain risk factors, all prospective living donors should be interviewed in a confidential and sensitive manner by a health-care professional competent to elicit information about behaviors that place persons at risk for HIV infection. Interviewers should ask direct questions about high-risk behavior.

4. For potential pediatric donors for whom maternal transmission of HIV is a consideration, the mother and, if possible, the father should be interviewed about behaviors that may have placed them at risk for acquiring HIV infection that could have been transmitted to their child.

5. Except where retrieval occurs by legal authorization, the next of kin or significant life partner of brain-dead or cadaveric donors should be interviewed in a confidential and sensitive manner by a health-care professional regarding potential HIV risk factors in the donor. Other family members, friends, and sex partners may also need to be interviewed, if available. When consent for removal of organs/tissue is required, at least the person signing the consent form should be interviewed. Other possible sources of information about behavioral risk factors may include hospital, police, and coroner's records, if available. When an interview is not performed, as allowed by legal authorization, the transplant surgeon should be fully informed that the donation was accepted, even though a direct interview with the next of kin or significant life partner was not performed.

6. If available, the medical records, including autopsy reports of all donors, should be reviewed for signs and symptoms associated with HIV infection and for evidence of high-risk behavior (e.g., male-to-male sexual contact, acquisition of sexually transmitted diseases, exchange of sex for money or drugs, injecting-drug use, or birth to a mother either at risk for or infected with HIV).

7. All prospective donors of organs, solid tissue, and semen should undergo a physical examination as close as possible before donation, with special attention to physical signs of HIV disease and injecting-drug use. The extent of the physical examination should be determined by the responsible medical officials according to the context of organ/tissue donation. Human milk banks should obtain a release from the primary health-care provider certifying that the prospective donor is in good health and does not constitute a risk to potential recipients.

8. As with donors of blood and plasma, prospective living organ, tissue, semen, and milk donors found after careful screening to be acceptable donors should sign

a consent statement indicating that they have reviewed and understand the information provided regarding the spread of HIV and have agreed not to donate should they be at potential risk for spreading HIV. The statement should also indicate that prospective donors understand that they must be tested for HIV as part of the donor-screening process and will be notified of positive results as specified by any existing state statutes, regulations, or guidelines. For acceptable brain-dead or cadaveric donors, procurement personnel should document that a careful attempt has been made to eliminate persons at high risk through available information, including interview of family members or significant life partners, physical examination, review of medical records, autopsy findings, and any other records that might provide information about high-risk behavior or possible HIV infection. For either type of donor, the statement should be included as part of a general checklist or donor evaluation form covering all important aspects of the donor evaluation and should be included in the transplant records or record of the procuring agency. All records generated by the interview should be kept confidential.

Donor Testing

1. For all prospective donors, a blood sample obtained before any transfusions were administered (during the current hospital admission for inpatients) should be collected as close to the time of retrieval of tissue as possible. Bone marrow donors must provide blood samples far enough in advance of marrow harvest to permit the tests to be performed and results reported before the recipient's preparative regimen (marrow ablatement) is begun. Samples should be tested for antibodies to both HIV-1 and HIV-2 by using FDA-licensed tests. Separate tests or a combination test for HIV-1 and HIV-2 may be used. All antibody-screening tests should be performed by EIA unless the condition of the recipient or donor dictates the use of a more rapid screening assay.

2. Transfusions and infusion of other fluids to the prospective donor might produce false-negative results because of hemodilution. Efforts should be made to perform HIV-antibody testing on the most recent pretransfusion/infusion specimen for which identity and quality can be ensured. Specimens should not be drawn immediately downstream from an intravenous site to prevent dilution with intravenous fluids.

   Posttransfusion/infusion specimens may be considered for testing after efforts to obtain a pretransfusion/infusion sample have been exhausted and posttransfusion/infusion samples have been assessed for evidence of dilution. The suitability of posttransfusion/infusion samples must consider a) the volume of the material transfused as a percentage of the patient's total blood volume and b) the amount of time between the last transfusion/infusion and the collection of the sample to be tested. An exchange of one total blood volume will reduce the concentration of an intravascular substance such as IgG to 35% of initial levels if there is no replacement from the extravascular space. More than 50% of total body IgG is extravascular, and reequilibration to normal levels of IgG should be nearly complete within 24 hours of a total blood volume exchange of albumin (*30*).

3. The HIV p24-antigen assay may identify a few of the rare donors who are HIV-infected, yet antibody-negative; however, studies examining the utility of this assay for screening organ/tissue donors are limited and currently do not allow a definitive recommendation on the use of this test (*19,24*). The utility of other assays such as PCR, which are currently experimental, should be considered for evaluation as they become available for clinical use. Those institutions choosing to use the HIV-1 p24-antigen assay should be aware that in populations with low prevalence (e.g., organ/tissue donors), a large percentage of persons who test repeatedly reactive (without confirmation with the neutralization assay) will be false positive. Consideration should also be given to the potential problems with decreased specificity when the assay is used to test postmortem samples (*19*).

4. The testing algorithm for HIV-antibody assays should be performed as described in the package insert with an initial test and, if reactive, a retest on the same specimen. However, the time constraints of some situations may not accommodate the delay of repeat testing by EIA as described in the package insert. In such extreme cases of lifesaving organ transplantation, the sample should be set up in triplicate in the initial EIA. A repeatedly reactive result (positive screening test) is defined as reactivity above the test cutoff in two or more of the three assays. When testing by EIA is impractical, a more rapid licensed test should be performed in triplicate. Testing by the conventional algorithm should be performed as early as possible, even if it follows the procurement and/or transplant of the organs or tissues.

5. Results of HIV testing for organ/tissue donors should be handled confidentially, in accordance with general medical practices and applicable federal and state statutes, regulations, and guidelines.

6. Prospective living donors should be notified if they are found through the screening process to be HIV infected. Because of the possibility of sexual or parenteral transmission, the spouse or known sex partners of brain-dead or cadaveric donors should be notified in accordance with state law. All notifications should be handled in a manner congruent with current recommendations regarding counseling, testing, and partner notification (*31,32*). Before the notification of these persons, transplant and procurement organizations should consult with their state health department concerning local notification policies.

   Also before notification, the repeatedly reactive screening assay should be confirmed with more specific supplemental tests. An aliquot of the original sample should be analyzed by using the following, more specific tests. For repeatedly reactive HIV-1 antibody EIAs, an HIV-1 Western blot or immunofluorescence assay should be performed. For repeatedly reactive HIV-1 antigen assays (if performed), a neutralization procedure must be performed. For HIV-2, no licensed supplemental test is available; however, consideration may be given to the use of research assays such as Western blot, immunofluorescence, radioimmune precipitation, and synthetic peptide-based EIA. Arrangements for HIV-2 supplemental testing may need to be made with either the state or local health department. For repeatedly reactive combination HIV-1 and HIV-2 assays, the published testing algorithm should be followed (*21*). When the results of any supplemental tests are unclear, the use of research assays should be considered.

Notification of HIV-infected prospective living donors or spouses/known sex partners of cadaveric donors should be done in accordance with state law and in a confidential and sensitive manner by staff competent in counseling and discussing positive HIV results and their implications. If such staff are not available in the organ/tissue procurement organization, arrangements should be made with other organizations such as health departments or clinics to provide appropriate notification.

7. When it is possible to properly obtain and store samples, one or more of the following samples from the donor should be saved for at least 5 years after the expiration date of the tissue: dried blood spots, a frozen buffy coat, spleen cells, lymph node cells, bone marrow, and an aliquot of serum. These samples can be examined if subsequent information indicates that the donor may have donated during the period after infection but before antibody seroconversion.

8. Confirmed positive HIV test results in a prospective organ/tissue donor should be reported to state health agencies if required by state law or regulation.

Donor Exclusion Criteria

Regardless of their HIV antibody test results, persons who meet any of the criteria listed below should be excluded from donation of organs or tissues unless the risk to the recipient of not performing the transplant is deemed to be greater than the risk of HIV transmission and disease (e.g., emergent, life-threatening illness requiring transplantation when no other organs/tissues are available and no other lifesaving therapies exist). In such a case, informed consent regarding the possibility of HIV transmission should be obtained from the recipient.

Behavior/History Exclusionary Criteria

1. Men who have had sex with another man in the preceding 5 years.

2. Persons who report nonmedical intravenous, intramuscular, or subcutaneous injection of drugs in the preceding 5 years.

3. Persons with hemophilia or related clotting disorders who have received human-derived clotting factor concentrates

4. Men and women who have engaged in sex in exchange for money or drugs in the preceding 5 years.

5. Persons who have had sex in the preceding 12 months with any person described in items 1–4 above or with a person known or suspected to have HIV infection.

6. Persons who have been exposed in the preceding 12 months to known or suspected HIV-infected blood through percutaneous inoculation or through contact with an open wound, nonintact skin, or mucous membrane.

7. Inmates of correctional systems. (This exclusion is to address issues such as difficulties with informed consent and increased prevalence of HIV in this population.)

Specific Exclusionary Criteria for Pediatric Donors

1. Children meeting any of the exclusionary criteria listed above for adults should not be accepted as donors.

2. Children born to mothers with HIV infection or mothers who meet the behavioral or laboratory exclusionary criteria for adult donors (regardless of their HIV status) should not be accepted as donors unless HIV infection can be definitely excluded in the child as follows:

   Children >18 months of age who are born to mothers with or at risk for HIV infection, who have not been breast fed within the last 12 months, and whose HIV antibody tests, physical examination, and review of medical records do not indicate evidence of HIV infection can be accepted as donors.

3. Children ≤18 months of age who are born to mothers with or at risk for HIV infection or who have been breast fed within the past 12 months should not be accepted as donors regardless of their HIV test results.

Laboratory and Other Medical Exclusionary Criteria

1. Persons who cannot be tested for HIV infection because of refusal, inadequate blood samples (e.g., hemodilution that could result in false-negative tests), or any other reasons.

2. Persons with a repeatedly reactive screening assay for HIV-1 or HIV-2 antibody regardless of the results of supplemental assays.

3. Persons whose history, physical examination, medical records, or autopsy reports reveal other evidence of HIV infection or high-risk behavior, such as a diagnosis of AIDS, unexplained weight loss, night sweats, blue or purple spots on the skin or mucous membranes typical of Kaposi's sarcoma, unexplained lymphadenopathy lasting >1 month, unexplained temperature >100.5 F (38.6 C) for >10 days, unexplained persistent cough and shortness of breath, opportunistic infections, unexplained persistent diarrhea, male-to-male sexual contact, sexually transmitted diseases, or needle tracks or other signs of parenteral drug abuse.

Inactivation of HIV in Organs/Tissues

Definitive recommendations cannot yet be made regarding inactivation of HIV in organs and tissues because of lack of information about potentially effective inactivation measures. Research should continue in this area. Efforts to evaluate the effect of certain processing techniques on tissue sterility and quality should be expanded to include virologic studies for HIV. Thus, until more is known, it is prudent to process bone and bone fragments and carefully evacuate all marrow components from whole bone whenever feasible.

Quarantine

For semen donations and, when possible, for tissue donations from living donors, the collection should be placed in frozen quarantine and the donor retested for

antibodies to HIV-1 and HIV-2 after 6 months (*15*). The quarantined material should be released only if the follow-up test results have been obtained and are negative.

Record Keeping for Tracking of Recipients and Tissues

1. Each establishment involved in the acquisition, processing, distribution, or storage of organs or tissues should have a graft identification system that allows the tracking of organs and tissues from the donor source to the recipient institution and vice versa. Furthermore, each establishment involved in the acquisition of organs or tissues from a single donor should have mechanisms in place to facilitate the communication between establishments for the purposes of tracking organs and tissues to recipients who should be notified if HIV transmission from donor source material is confirmed. Procurement, processing, distribution, and storage centers should keep accurate records of the distribution of each organ/tissue according to the donor identification number, tissue type and identifying number, and identifying information for the receiving center, along with dates of procurement and distribution. Records should be kept a minimum of 10 years after expiration of tissue.

2. The transplantation center, hospital, physician, or dentist should keep accurate records of all organs/tissues received and the disposition of each. These records must be separate from patients' medical records (e.g., in a log book) so that this information is easily obtainable should tracking be necessary. Recorded information should include the organ/tissue type; donor identification number; name of procurement or distribution center supplying the organ/tissue; recipient-identifying information; name of recipient's physician or dentist; and dates of a) receipt by the center and b) either transplantation to the recipient or further distribution.

3. The donor identification number and organ or tissue type should be recorded in the recipient's transplant/medical/dental record.

Testing and Reporting of Recipients

1. Health-care providers for transplant recipients and the recipients themselves should be aware of the small but potential risk of infections, including HIV, from transplanted organs and tissues. The recipient's informed consent to the transplant should include acknowledgment of the risks, including transmission of HIV and other infections.

2. Until the risk for HIV transmission from screened donors has been clarified, recipients of solid organs should be routinely advised to be tested for HIV immediately before transplantation and at 3 months following the transplant. Testing of recipients should be done with consent of the recipient and should not be mandatory. Recipients of tissues other than solid organs do not require routine testing for HIV following receipt of the tissue from appropriately screened donors. Results of HIV testing of organ recipients should be collected and analyzed by the Scientific Registry for Transplant Recipients. (If data indicate no benefit from recipient testing, then this recommendation for recipient testing may be omitted in a revision of these guidelines.)

3. If a transplant recipient is found to be infected with HIV, the transplant center or health-care provider should, consistent with state law, immediately notify the state health department and the organization from which the tissue was obtained. HIV infection in a solid-organ recipient should also be reported to the Scientific Registry for Transplant Recipients.

Recall of Stored Tissue and Tracking of Recipients of Organs/Tissue from HIV-Infected Donors

1. Upon being notified that an organ/tissue recipient is infected with HIV, the organ/tissue collection center, in collaboration with the state or local health department and with assistance from CDC, is responsible for determining as soon as possible whether the donor was HIV-infected. This is done by determining the HIV-infection status of other recipients of organs/tissues (particularly those recipients of organs and fresh-frozen bone) and by laboratory testing of stored donor material. Experimental diagnostic laboratory assays such as PCR may be useful in these situations and should be used when they become available.

2. If evidence suggests HIV infection in the donor either from testing of stored donor specimens or by finding HIV infection in other recipients, all other recipients of that donor's tissue or organs should be notified through their transplanting physician and informed of the likelihood of HIV exposure and advised to undergo HIV testing.

3. HIV-infected recipients should be counseled about their need for medical evaluation and about prevention of HIV transmission to others. They should also be advised to inform their sex or needle-sharing partners of their potential risk and need for HIV counseling and testing. HIV-infected women should be informed of the risk of transmission of HIV to their children born after the transplant and be advised to have these children evaluated and to avoid breast-feeding. Pregnant women should receive pregnancy counseling about HIV.

4. All stored organs/tissues from a donor found to be HIV-infected should be retrieved and quarantined immediately and either used only for research purposes or destroyed, except when the transplantation of an indispensable organ/tissue is necessary to save the patient's life.

[61 FR 19745, May 2, 1996]

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

Subpart A—General Provisions

Sec.
488.1 Definitions.
488.2 Statutory basis.
488.3 Conditions of participation; conditions for coverage; and long-term care requirements.
488.4 Application and reapplication procedures for accreditation organizations.
488.5 Effect of JCAHO or AOA accreditation of hospitals.
488.6 Other national accreditation programs for hospitals and other providers and suppliers.
488.7 Validation survey.
488.8 Federal review of accreditation organizations.
488.9 Onsite observation of accreditation organization operations.
488.10 State survey agency review: Statutory provisions.
488.11 State survey agency functions.
488.12 Effect of survey agency certification.
488.14 Effect of PRO review.
488.18 Documentation of findings.
488.20 Periodic review of compliance and approval.
488.24 Certification of noncompliance.
488.26 Determining compliance.