§ 486.308 Designation of one OPO for each service area.
§ 486.309 Re-certification from August 1, 2006 through July 31, 2010.
§ 486.310 Changes in control or ownership or service area.

Re-certification and De-certification

§ 486.312 De-certification.
§ 486.314 Appeals.
§ 486.316 Re-certification and competition processes.

ORGAN PROCUREMENT ORGANIZATION OUTCOME REQUIREMENTS

§ 486.318 Condition: Outcome measures.

ORGAN PROCUREMENT ORGANIZATION PROCESS PERFORMANCE MEASURES

§ 486.320 Condition: Participation in Organ Procurement and Transplantation Network.
§ 486.322 Condition: Relationships with hospitals, critical access hospitals, and tissue banks.
§ 486.324 Condition: Administration and governing body.
§ 486.326 Condition: Human resources.
§ 486.328 Condition: Reporting of data.
§ 486.330 Condition: Information management.
§ 486.342 Condition: Requesting consent.
§ 486.344 Condition: Evaluation and management of potential donors and organ placement and recovery.
§ 486.346 Condition: Organ preparation and transport.
§ 486.348 Condition: Quality assessment and performance improvement (QAPI).

AUTHORITY: Secs. 1102, 1138(b), 1871 of the Social Security Act, section 371(b) of the Public Health Service Act (42 U.S.C. 273).

Subpart A—General Provisions

§ 486.1 Basis and scope.

(a) Statutory basis. This part is based on the following sections of the Act:
1102 and 1138(b), 1871 of the Social Security Act, section 371(b) of the Public Health Service Act—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.

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(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.


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).


§ 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 the 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.

§ 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., be (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.

§ 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 paragraphs (a)(1), (2), (3), or (4) of this section:

(1) Successful completion of a program of formal training in X-ray technology in a school approved by the Joint Review Committee on Education in Radiologic Technology (JRCERT), 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.