

§ 486.1

- 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.
- 486.309 Recertification from January 1, 2002 through December 31, 2005.
- 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 CMS.

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,

42 CFR Ch. IV (10–1–03 Edition)

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