to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room where the procedure is performed. During a Public Health Emergency, as defined in § 400.200 of this chapter, the presence of the physician includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider.

(2) For services furnished under arrangement in nonhospital locations, ''direct supervision'' means the definition specified in § 410.32(b)(3)(ii).

(f) The rules for clinical diagnostic laboratory tests set forth in §§ 410.32(a) and (d)(2) through (d)(4) of this subpart are applicable to those tests when furnished in hospitals and CAHs.

[51 FR 41339, Nov. 14, 1986, as amended at 58 FR 30668, May 26, 1993; 63 FR 26307, May 12, 1998; 65 FR 18536, Apr. 7, 2000; 66 FR 58809, Nov. 23, 2001; 74 FR 60680, Nov. 20, 2009; 75 FR 72259, Nov. 24, 2010; 85 FR 19286, Apr. 6, 2020]

§ 410.29 Limitations on drugs and biologicals.

Medicare part B does not pay for the following:

(a) Except as provided in § 410.28(a) for outpatient diagnostic services and § 410.63(b) for blood clotting factors, and except for EPO, any drug or biological which is usually self-administered by the patient.

(b) Any drug product that meets all of the following conditions:

(1) The drug product was approved by the Food and Drug Administration (FDA) before October 10, 1962.

(2) The drug product is available only through prescription.

(3) The drug product is the subject of a notice of opportunity for hearing issued under section 505(e) of the Federal Food, Drug, and Cosmetic Act and published in the FEDERAL REGISTER on a proposed order of FDA to withdraw its approval for the drug product because it has determined that the product is less than effective for all its labeled indications.

(4) The drug product is presently not subject to a determination by FDA, made under its efficacy review program, that there is a compelling justification of the drug product's medical need. (21 CFR 310.6 contains an explanation of the efficacy review program.)

(c) Any drug product that is identical, related, or similar, as defined in 21 CFR 310.6, to a drug product that meets the conditions of paragraph (b) of this section.

[51 FR 41339, Nov. 14, 1986, as amended at 55 FR 22790, June 4, 1990; 56 FR 43709, Sept. 4, 1991; 80 FR 70602, Nov. 13, 2015]

§ 410.30 Prescription drugs used in immunosuppressive therapy.

(a) *Scope.* Payment may be made for prescription drugs used in immunosuppressive therapy that have been approved for marketing by the FDA and that meet one of the following conditions:

(1) The approved labeling includes the indication for preventing or treating the rejection of a transplanted organ or tissue.

(2) The approved labeling includes the indication for use in conjunction with immunosuppressive drugs to prevent or treat rejection of a transplanted organ or tissue.

(3) Have been determined by a carrier (in accordance with part 421, subpart C of this chapter), in processing a Medicare claim, to be reasonable and necessary for the specific purpose of preventing or treating the rejection of a patient's transplanted organ or tissue, or for use in conjunction with immunosuppressive drugs for the purpose of preventing or treating the rejection of a patient's transplanted organ or tissue. (In making these determinations, the carriers may consider factors such as authoritative drug compendia, current medical literature, recognized standards of medical practice, and professional medical publications.)

(b) *Eligibility.* For drugs furnished on or after December 21, 2000, coverage is available only for prescription drugs used in immunosuppressive therapy, furnished to an individual who received an organ or tissue transplant for which Medicare payment is made, provided the individual is eligible to receive Medicare Part B benefits.