

AUTHORITY: Secs. 1102, 1861, 1862(a), 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 1302, 1395x, 1395y(a), 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

Subpart A [Reserved]

Subpart B—Medical Services Coverage Decisions That Relate to Health Care Technology

AUTHORITY: Secs. 1102, 1862 and 1871 of the Social Security Act as amended (42 U.S.C.1302, 1395y, and 1395hh).

SOURCE: 60 FR 48423, Sept. 19, 1995, unless otherwise noted.

§ 405.201 Scope of subpart and definitions.

(a) *Scope.* This subpart establishes that—

(1) CMS uses the FDA categorization of a device as a factor in making Medicare coverage decisions; and

(2) CMS may consider for Medicare coverage certain devices with an FDA-approved investigational device exemption (IDE) that have been categorized as non-experimental/investigational (Category B).

(b) *Definitions.* As used in this subpart—

Class I refers to devices for which the general controls of the Food, Drug, and Cosmetic Act, such as adherence to good manufacturing practice regulations, are sufficient to provide a reasonable assurance of safety and effectiveness.

Class II refers to devices that, in addition to general controls, require special controls, such as performance standards or postmarket surveillance, to provide a reasonable assurance of safety and effectiveness.

Class III refers to devices that cannot be classified into Class I or Class II because insufficient information exists to determine that either special or general controls would provide reasonable assurance of safety and effectiveness. Class III devices require premarket approval.

Contractors refers to carriers, fiscal intermediaries, and other entities that contract with CMS to review and adjudicate claims for Medicare services.

Experimental/investigational (Category A) device refers to an innovative device believed to be in Class III for which “absolute risk” of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved and the FDA is unsure whether the device type can be safe and effective).

IDE stands for investigational device exemption. An FDA-approved IDE application permits a device, which would otherwise be subject to marketing clearance, to be shipped lawfully for the purpose of conducting a clinical trial in accordance with 21 U.S.C. 360j(g) and 21 CFR parts 812 and 813.

Non-experimental/investigational (Category B) device refers to a device believed to be in Class I or Class II, or a device believed to be in Class III for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type.

PMA stands for “premarket approval” and refers to a marketing application for a Class III device, which includes all information submitted with or incorporated by reference in the application in accordance with 21 U.S.C. 360e and 360j and 21 CFR 814.3(e).

Sponsor refers to a person or entity that initiates, but does not conduct, an investigation under an IDE.

§ 405.203 FDA categorization of investigational devices.

(a) The FDA assigns a device with an FDA-approved IDE to one of two categories:

(1) Experimental/Investigational (Category A) Devices.

(2) Non-Experimental/Investigational (Category B) Devices.

(b) The FDA notifies CMS, when it notifies the sponsor, that the device is categorized by FDA as experimental/investigational (Category A) or non-experimental/investigational (Category B).