§ 405.203

paragraphs (a)(2) and (b); and by adding paragraph (a)(3), effective Jan. 1, 2015. For the convenience of the user, the added and revised text is set forth as follows:

§ 405.201 Scope of subpart and definitions.

(a) * * *

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

(3) CMS identifies criteria for coverage of items and services furnished in IDE studies.

(b) Definitions. As used in this subpart—

Category A (Experimental) device refers to a device 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.

Category B (Non-experimental/investigational) device refers to a device for which the incremental risk is the primary risk in question (that is, initial 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 premarket approval or clearance for that device type.

ClinicalTrials.gov refers to the National Institutes of Health’s National Library of Medicine’s online registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.

Contractors refers to Medicare Administrative Contractors and other entities that contract with CMS to review and adjudicate claims for Medicare payment of items and services.

Investigational device exemption (IDE) refers to an FDA-approved IDE application that permits a device, which would otherwise be subject to marketing approval or clearance, to be shipped lawfully for the purpose of conducting a clinical study in accordance with 21 U.S.C. 360(j) and 21 CFR part 812.

Routine care items and services refers to items and services that are otherwise generally available to Medicare beneficiaries (that is, a benefit category exists, it is not statutorily excluded, and there is no national noncoverage decision) that are furnished during a clinical study and that would be otherwise furnished even if the beneficiary were not enrolled in a clinical study.

§ 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).

(c) CMS uses the categorization of the device as a factor in making Medicare coverage decisions.

Effective Date Note: At 78 FR 74809, Dec. 10, 2013, §405.203 was amended by revising paragraphs (a)(1) and (2) and (b), effective Jan. 1, 2015. For the convenience of the user, the revised text is set forth as follows:

§ 405.203 FDA categorization of investigational devices.

(a) * * *

1. Category A (Experimental) devices.
2. Category B (Non-experimental) devices.

(b) The FDA notifies CMS, when it notifies the sponsor, that the device is categorized by FDA as Category A (Experimental) or Category B (Nonexperimental).

* * * * *

§ 405.205 Coverage of a non-experimental/investigational (Category B) device.

(a) For any device that meets the requirements of the exception at §411.15(o) of this chapter, the following procedures apply:

1. The FDA notifies CMS, when it notifies the sponsor, that the device is categorized by FDA as non-experimental/investigational (Category B).
2. CMS uses the categorization of the device as a factor in making Medicare coverage decisions.

If the FDA becomes aware that a categorized device no longer meets the requirements of the exception at §411.15(o) of this chapter, the FDA notifies the sponsor and CMS and the procedures described in paragraph (a)(2) of this section apply.

Effective Date Note: At 78 FR 74809, Dec. 10, 2013, §405.205 by revising the section heading and paragraph (a)(1), effective Jan. 1, 2015. For the convenience of the user, the revised text is set forth as follows: