

## Centers for Medicare & Medicaid Services, HHS

§ 419.50

solely on the basis of meeting any specific factor.

[78 FR 75196, Dec. 10, 2013, as amended at 79 FR 67031, Nov. 10, 2014; 80 FR 70606, Nov. 13, 2015; 81 FR 79879, Nov. 14, 2016; 82 FR 52637, Nov. 13, 2017; 82 FR 59497, Dec. 14, 2017; 83 FR 59179, Nov. 21, 2018; 85 FR 86302, Dec. 29, 2020; 86 FR 63993, Nov. 16, 2021; 87 FR 72291, Nov. 23, 2022]

### § 419.47 Coding and Payment for Category B Investigational Device Exemption (IDE) Studies.

(a) *Creation of a new HCPCS code for Category B IDE Studies.* CMS will create a new HCPCS code, or revise an existing HCPCS code, to describe a Category B IDE study, which will include both the treatment and control arms, related device(s) of the study, as well as routine care items and services, as specified under § 405.201 of this chapter, when CMS determines that:

(1) The Medicare coverage IDE study criteria in § 405.212 of this chapter are met; and

(2) A new or revised code is necessary to preserve the scientific validity of such a study, such as by preventing the unblinding of the study.

(b) *Payment for Category B IDE Studies.* Where CMS creates a new HCPCS code or revises an existing HCPCS code under paragraph (a) of this section, CMS will:

(1) Make a single packaged payment for the HCPCS code that includes payment for the investigational device, placebo control, and routine care items and services of a Category B IDE study, as specified under § 405.201 of this chapter; and

(2) Calculate the single packaged payment rate for the HCPCS code based on the average resources utilized for each study participant, including the frequency with which the investigational device is used in the study population.

[87 FR 72291, Nov. 23, 2022]

### § 419.48 Definition of excepted items and services.

(a) Excepted items and services are items or services that are furnished on or after January 1, 2017—

(1) By a dedicated emergency department (as defined at § 489.24(b) of this chapter); or

(2) By an excepted off-campus provider-based department defined in paragraph (b) of this section that has not impermissibly relocated or changed ownership.

(b) For the purpose of this section, “excepted off-campus provider-based department” means a “department of a provider” (as defined at § 413.65(a)(2) of this chapter) that is located on the campus (as defined in § 413.65(a)(2) of this chapter) or within the distance described in such definition from a “remote location of a hospital” (as defined in § 413.65(a)(2) of this chapter) that meets the requirements for provider-based status under § 413.65 of this chapter. This definition also includes an off-campus department of a provider that was furnishing services prior to November 2, 2015 that were billed under the OPPS in accordance with timely filing limits.

(c) Payment for items and services that do not meet the definition in paragraph (a) of this section will generally be made under the Medicare Physician Fee Schedule on or after January 1, 2017.

[81 FR 79880, Nov. 14, 2016; 82 FR 36, Jan. 3, 2017]

## Subpart E—Updates

### § 419.50 Annual review.

(a) *General rule.* Not less often than annually, CMS reviews and updates groups, relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

(b) *Consultation requirement.* CMS will consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise CMS concerning) the clinical integrity of the groups and weights. The panel may use data collected or developed by entities and organizations (other than the Department of Health and Human Services) in conducting the review.

(c) *Effective dates.* CMS conducts the first annual review under paragraph (a) of this section in 2001 for payments made in 2002.