

8 CCR 9789.38 (As of September 15, 2011)

(The underlined text reflects amendments made in accordance with the administrative director Orders effective September 15, 2011.)

The federal regulations as incorporated by reference and/or referred to in Sections 9789.30 through 9789.36 are set forth below in numerical order.

42 C.F.R. § 419.2

Basis of payment.

(a) Unit of payment. Under the hospital outpatient prospective payment system, predetermined amounts are paid for designated services furnished to Medicare beneficiaries. These services are identified by codes established under the Centers for Medicare & Medicaid Services Common Procedure Coding System (HCPCS). The prospective payment rate for each service or procedure for which payment is allowed under the hospital outpatient prospective payment system is determined according to the methodology described in subpart C of this part. The manner in which the Medicare payment amount and the beneficiary copayment amount for each service or procedure are determined is described in subpart D of this part.

(b) Determination of hospital outpatient prospective payment rates: Included costs. The prospective payment system establishes a national payment rate, standardized for geographic wage differences, that includes operating and capital-related costs that are directly related and integral to performing a procedure or furnishing a service on an outpatient basis. In general, these costs include, but are not limited to

- (1) Use of an operating suite, procedure room, or treatment room;
- (2) Use of recovery room;
- (3) Use of an observation bed;
- (4) Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations;
- (5) Supplies and equipment for administering and monitoring anesthesia or sedation;
- (6) Intraocular lenses (IOLs);
- (7) Incidental services such as venipuncture;
- (8) Capital-related costs;
- (9) Implantable items used in connection with diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests;
- (10) Durable medical equipment that is implantable;
- (11) Implantable prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of these devices; and;
- (12) Costs incurred to procure donor tissue other than corneal tissue.

(c) Determination of hospital outpatient prospective payment rates: Excluded costs. The following costs are excluded from the hospital outpatient prospective payment system.

- (1) The costs of direct graduate medical education activities as described in §413.86 of this chapter.
- (2) The costs of nursing and allied health programs as described in §413.86 of this chapter.
- (3) The costs associated with interns and residents not in approved teaching programs as described in §415.202 of this chapter.
- (4) The costs of teaching physicians attributable to Part B services for hospitals that elect cost-based reimbursement for teaching physicians under §415.160.

(5) The reasonable costs of anesthesia services furnished to hospital outpatients by qualified nonphysician anesthetists (certified registered nurse anesthetists and anesthesiologists' assistants) employed by the hospital or obtained under arrangements, for hospitals that meet the requirements under §412.113(c) of this chapter.

(6) Bad debts for uncollectible deductibles and coinsurances as described in §413.80(b) of this chapter.

(7) Organ acquisition costs paid under Part B.

(8) Corneal tissue acquisition costs.

42 C.F.R. § 419.32

Calculation of prospective payment rates for hospital outpatient services.

(a) Conversion factor for 1999. CMS calculates a conversion factor in such a manner that payment for hospital outpatient services furnished in 1999 would have equaled the base expenditure target calculated in § 419.30, taking into account APC group weights and estimated service frequencies and reduced by the amounts that would be payable in 1999 as outlier payments under § 419.43(d) and transitional pass-through payments under § 419.43(e).

(b) Conversion factor for calendar year 2000 and subsequent years. (1) Subject to paragraph (b)(2) of this section, the conversion factor for a calendar year is equal to the conversion factor calculated for the previous year adjusted as follows:

(i) For calendar year 2000, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act reduced by one percentage point.

(ii) For calendar year 2001 --

(A) For services furnished on or after January 1, 2001 and before April 1, 2001, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act reduced by one percentage point; and

(B) For services furnished on or after April 1, 2001 and before January 1, 2002, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, and increased by a transitional percentage allowance equal to 0.32 percent.

(iii) For the portion of calendar year 2002 that is affected by these rules, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act reduced by one percentage point, without taking into account the transitional percentage allowance referenced in § 419.32(b)(ii)(B).

(iv) For calendar year 2003 and subsequent years, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act.

(2) Beginning in calendar year 2000, CMS may substitute for the hospital inpatient market basket percentage in paragraph (b) of this section a market basket percentage increase that is determined and applied to hospital outpatient services in the same manner that the hospital inpatient market basket percentage increase is determined and applied to inpatient hospital services.

(c) Payment rates. The payment rate for services and procedures for which payment is made under the hospital outpatient prospective payment system is the product of the conversion factor calculated under paragraph (a) or paragraph (b) of this section and the relative weight determined under § 419.31(b).

(d) Budget neutrality.

(1) CMS adjusts the conversion factor as needed to ensure that updates and adjustments under § 419.50(a) are budget neutral.

(2) In determining adjustments for 2004 and 2005, CMS will not take into account any additional expenditures per section 1833(t)(14) of the Act that would not have been made but for enactment of section 621 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

Effective January 1, 2011, Section 419.32 is amended by revising paragraph (b)(1)(iv) to read as follows:

(b) * * *

(1) * * *

(iv)(A) For calendar year 2003 and subsequent years, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act.

(B) The percentage increase determined under paragraph (b)(1)(iv)(A) of this section is reduced by the following for the specific calendar year:

(1) For calendar year 2010, 0.25 percentage point; and

(2) For calendar year 2011, 0.25 percentage point.

42 C.F.R. § 419.43

Adjustments to national program payment and beneficiary copayment amounts.

(a) General rule. CMS determines national prospective payment rates for hospital outpatient department services and determines a wage adjustment factor to adjust the portion of the APC payment and national beneficiary copayment amount attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner.

(b) Labor-related portion of payment and copayment rates for hospital outpatient services. CMS determines the portion of hospital outpatient costs attributable to labor and labor-related costs (known as the "labor-related portion" of hospital outpatient costs) in accordance with § 419.31(c)(1).

(c) Wage index factor. CMS uses the hospital inpatient prospective payment system wage index established in accordance with part 412 of this chapter to make the adjustment referred to in paragraph (a) of this section.

(d) Outlier adjustment -- (1) General rule. Subject to paragraph (d)(4) of this section, CMS provides for an additional payment for a hospital outpatient service (or group of services) not excluded under paragraph (f) of this section for which a hospital's charges, adjusted to cost, exceed the following:

(i) A fixed multiple of the sum of --

(A) The applicable Medicare hospital outpatient payment amount determined under § 419.32(c), as adjusted under § 419.43 (other than for adjustments under this paragraph (d) or paragraph (e) of this section); and

(B) Any transitional pass-through payment under paragraph (e) of this section.

(ii) At the option of CMS, a fixed dollar amount.

(2) Amount of adjustment. The amount of the additional payment under paragraph (d)(1) of this section is determined by CMS and approximates the marginal cost of care beyond the applicable cutoff point under paragraph (d)(1) of this section.

(3) Limit on aggregate outlier adjustments -- (i) In general. The total of the additional payments made under this paragraph (d) for covered hospital outpatient department services furnished in a year (as estimated by CMS before the beginning of the year) may not exceed the applicable percentage specified in paragraph (d)(3)(ii) of this section of the total program payments (sum of both the Medicare and beneficiary payments to the hospital) estimated to be made under this part for all hospital outpatient services furnished in that year. If this paragraph is first applied to less than a full year, the limit applies only to the portion of the year.

(ii) Applicable percentage. For purposes of paragraph (d)(3)(i) of this section, the term "applicable percentage" means a percentage specified by CMS up to (but not to exceed) --

(A) For a year (or portion of a year) before 2004, 2.5 percent; and

(B) For 2004 and thereafter, 3.0 percent.

(4) Transitional authority. In applying paragraph (d)(1) of this section for hospital outpatient services furnished before January 1, 2002, CMS may --

(i) Apply paragraph (d)(1) of this section to a bill for these services related to an outpatient encounter (rather than for a specific service or group of services) using hospital outpatient payment amounts and transitional pass-through payments covered under the bill; and

(ii) Use an appropriate cost-to-charge ratio for the hospital or CMHC (as determined by CMS), rather than for specific departments within the hospital.

(e) Budget neutrality. CMS establishes payment under paragraph (d) of this section in a budget-neutral manner excluding services and groups specified in paragraph (f) of this section.

(f) Excluded services and groups. Drugs and biologicals that are paid under a separate APC and devices of brachytherapy, consisting of a seed or seeds (including radioactive source) are excluded from qualification for outlier payments.

Effective January 1, 2006, Section 419.43 is amended by adding a new paragraph (g) to read as follows:

(g) *Payment adjustment for certain rural hospitals.* (1) *General rule.* CMS provides for additional payment for covered hospital outpatient services not excluded under paragraph (g)(4) of this section, furnished on or after January 1, 2006, if the hospital—

(i) Is a sole community hospital under § 412.92 of this chapter; and

(ii) Is located in a rural area as defined in § 412.64(b) of this chapter or is treated as being located in a rural area under §412.103 of this chapter.

(2) *Amount of adjustment.* The amount of the additional payment under paragraph (g)(1) of this section is determined by CMS and is based on the difference between costs incurred by hospitals that meet the criteria in paragraphs (g)(1)(i) and (g)(1)(ii) of this section and costs incurred by hospitals located in urban areas.

(3) *Budget neutrality.* CMS establishes the payment adjustment under paragraph (g)(2) of this section in a budget neutral manner, excluding services and groups specified in paragraph (g)(4) of this section.

(4) *Excluded services and groups.* Drugs and biologicals that are paid under a separate APC and devices of brachytherapy consisting of a seed or seeds (including a radioactive source) are excluded from qualification for the payment adjustment in paragraph (g)(2) of this section.

(5) *Copayment.* The payment adjustment in paragraph (g)(2) of this section is applied before calculating copayment amounts.

(6) *Outliers.* The payment adjustment in paragraph (g)(2) of this section is applied before calculating outlier payments.

Effective January 1, 2007, Section 419.43 is amended by—

_ a. Revising paragraph (f).

_ b. Revising paragraph (g)(1)(i).

_ c. Adding a new paragraph (h).

The revision and addition read as follows:

(f) *Excluded services and groups.* Drugs and biologicals that are paid under a separate APC are excluded from qualification for outlier payments.

(g) * * *

(1) * * *

(i) Is a sole community hospital under § 412.92 of this chapter or is an essential access community hospital under § 412.109 of this chapter; and

* * * * *

(h) *Applicable adjustments to conversion factor for CY 2009 and for subsequent calendar years—*

(1) *General rule.* For CY 2009 and for subsequent calendar years, the applicable adjustment to the conversion factor specified in §419.32(b)(1)(iv) is reduced by 2.0 percentage points for any hospital that fails to meet the standards for reporting of hospital outpatient quality measures as established by the Secretary for the corresponding calendar year.

(2) *Limitation.* Any reduction to a hospital's adjustment to its conversion factor specified in § 419.32(b)(1)(iv) which occurs as a result of paragraph (h)(1) of this section will apply only to the calendar year involved and will not be taken into account in computing that hospital's applicable adjustment for a subsequent calendar year.

(3) *Budget neutrality.* For CY 2009 and for each subsequent calendar year, CMS makes an adjustment to the conversion factor, so that estimated aggregate payments under the OPSS for such calendar year are not affected by any reductions to hospital adjustments which occur as a result of paragraph (h)(1) of this section.

Effective January 1, 2008, Section 419.43 is amended by revising paragraph (g)(4) to read as follows:

(g) * * *

(4) *Excluded services and groups.* Drugs and biologicals that are paid under a separate APC and devices paid under §419.66 are excluded from qualification for the payment adjustment in paragraph (g)(2) of this section.

Effective January 1, 2009, 15. Section 419.43 is amended by—

- a. In paragraph (d)(1)(i)(B), removing the phrase “paragraph (e) of this section” and adding in its place the cross-reference “§ 419.66”.
- b. Adding new paragraphs (d)(5) and (d)(6).
- c. Revising paragraph (f).
- d. Revising paragraph (g)(4).
- e. Adding a new paragraph (h)(4).

The additions and revisions read as follows:

(d) * * *

(5) *Cost-to-charge ratios for calculating charges adjusted to cost.* For hospital outpatient services (or groups of services) as defined in paragraph (d)(1) of this section performed on or after January 1, 2009—

(i) CMS may specify an alternative to the overall ancillary cost-to-charge ratio otherwise applicable under paragraph (d)(5)(ii) of this section. A hospital may also request that its Medicare contractor use a different (higher or lower) cost-to-charge ratio based on substantial evidence presented by the hospital. Such a request must be approved by the CMS.

(ii) The overall ancillary cost-to-charge ratio applied at the time a claim is processed is based on either the most recent settled cost report or the most recent tentative settled cost report, whichever is from the latest cost reporting period.

(iii) The Medicare contractor may use a statewide average cost-to-charge ratio if it is unable to determine an accurate overall ancillary cost-to-charge ratio for a hospital in one of the following circumstances:

(A) A new hospital that has not yet submitted its first Medicare cost report. (For purposes of this paragraph, a new hospital is defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18 of this chapter.)

(B) A hospital whose overall ancillary cost-to-charge ratio is in excess of 3 standard deviations above the corresponding national geometric mean. This mean is recalculated annually by CMS and published in the annual notice of prospective payment rates issued in accordance with § 419.50(a).

(C) Any other hospital for whom accurate data to calculate an overall ancillary cost-to-charge ratio are not available to the Medicare contractor.

(6) *Reconciliation.* For hospital outpatient services furnished during cost reporting periods beginning on or after January 1, 2009—

(i) Any reconciliation of outlier payments will be based on an overall ancillary cost-to-charge ratio calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the service is settled.

(ii) At the time of any reconciliation under paragraph (d)(6)(i) of this section, outlier payments may be adjusted to account for the time value of any underpayments or overpayments. Any adjustment will be based on a widely available index to be established in advance by CMS, and will be applied from the midpoint of the cost reporting period to the date of reconciliation.

* * * * *

(f) *Excluded services and groups.* The following services or groups are excluded from qualification for the payment adjustment under paragraph (d)(1) of this section:

(1) Drugs and biologicals that are paid under a separate APC; and

(2) Items and services paid at charges adjusted to costs by application of a hospital-specific cost-to-charge ratio.

(g) * * *

(4) *Excluded services and groups.* The following services or groups are excluded from qualification for the payment adjustment in paragraph (g)(2) of this section:

(i) Drugs and biologicals that are paid under a separate APC;

(ii) Devices paid under 419.66; and

(iii) Items and services paid at charges adjusted to costs by application of a hospital-specific cost-to-charge ratio.

* * * * *

(h) * * *

(4) *Beneficiary copayment.* The beneficiary copayment for services to which the adjustment to the conversion factor specified under paragraph (h)(1) of this section applies is the product of the national beneficiary copayment amount calculated under § 419.41 and the ratio of the adjusted conversion factor calculated under paragraph (h)(1) of this section divided by the conversion factor specified under § 419.32(b)(1).

Effective January 1, 2011, Section 419.43 is amended by revising paragraph (c) to read as follows:

(c) *Wage index factor.*—(1) CMS uses the hospital inpatient prospective payment system wage index established in accordance with Part 412 of this chapter to make the adjustment specified under paragraph (a) of this section.

(2) For services furnished beginning January 1, 2011, the wage index factor provided for in paragraph (c)(1) of this section applicable to any hospital outpatient department that is located in a frontier State, as defined in § 412.64(m) of this chapter, may not be less than 1.00.

(3) The additional payments made under the provisions of paragraph (c)(2) of this section are not implemented in a budget neutral manner.

(a) Multiple surgical procedures. When more than one surgical procedure for which payment is made under the hospital outpatient prospective payment system is performed during a single surgical encounter, the Medicare program payment amount and the beneficiary copayment amount are based on --

- (1) The full amounts for the procedure with the highest APC payment rate; and
- (2) One-half of the full program and the beneficiary payment amounts for all other covered procedures.

(b) Terminated procedures. When a surgical procedure is terminated prior to completion due to extenuating circumstances or circumstances that threaten the well-being of the patient, the Medicare program payment amount and the beneficiary copayment amount are based on --

(1) The full amounts if the procedure is discontinued after the induction of anesthesia or after the procedure is started; or

(2) One-half of the full program and the beneficiary coinsurance amounts if the procedure is discontinued after the patient is prepared for surgery and taken to the room where the procedure is to be performed but before anesthesia is induced.]

Effective January 1, 2008, Section 419.44 is amended by—

_ a. Revising the section heading.

_ b. Revising paragraph (b).

The revisions and addition read as follows:

§ 419.44 Payment reductions for procedures.

* * * * *

(b) *Interrupted procedures.* When a procedure is terminated prior to completion due to extenuating circumstances or circumstances that threaten the well-being of the patient, the Medicare program payment amount and the beneficiary copayment amount are based on—

(1) The full program and beneficiary copayment amounts if the procedure for which anesthesia is planned is discontinued after the induction of anesthesia or after the procedure is started;

(2) One-half the full program and the beneficiary copayment amounts if the procedure for which anesthesia is planned is discontinued after the patient is prepared and taken to the room where the procedure is to be performed but before anesthesia is induced; or

(3) One-half of the full program and beneficiary copayment amounts if a procedure for which anesthesia is not planned is discontinued after the patient is prepared and taken to the room where the procedure is to be performed.

42 C.F.R. § 419.62

Transitional pass-through payments: General rules.

(a) General. CMS provides for additional payments under §§ 419.64 and 419.66 for certain innovative medical devices, drugs, and biologicals.

(b) Budget neutrality. CMS establishes the additional payments under §§ 419.64 and 419.66 in a budget neutral manner.

(c) Uniform prospective reduction of pass-through payments. (1) If CMS estimates before the beginning of a calendar year that the total amount of pass-through payments under §§ 419.64 and 419.66 for the year would exceed the applicable percentage (as described in paragraph (c)(2) of this section) of the total amount of Medicare payments under the outpatient prospective payment system. CMS will reduce, pro rata, the amount of each of the additional payments under §§ 419.64 and 419.66 for that year to ensure that the applicable percentage is not exceeded.

(2) The applicable percentages are as follows:

(i) For a year before CY 2004, the applicable percentage is 2.5 percent.

(ii) For 2004 and subsequent years, the applicable percentage is a percentage specified by CMS up to (but not to exceed) 2.0 percent.

(d) CY 2002 incorporated amount. For the portion of CY 2002 affected by these rules, CMS incorporated 75 percent of the estimated pass-through costs (before the incorporation and any pro rata reduction) for devices into the procedure APCs associated with these devices.

42 C.F.R. § 419.64

Transitional pass-through payments: drugs and biologicals.

(a) Eligibility for pass-through payment. CMS makes a transitional pass-through payment for the following drugs and biologicals that are furnished as part of an outpatient hospital service:

(1) Orphan drugs. A drug or biological that is used for a rare disease or condition and has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act if payment for the drug or biological as an outpatient hospital service was being made on August 1, 2000.

(2) Cancer therapy drugs and biologicals. A drug or biological that is used in cancer therapy, including, but not limited to, a chemotherapeutic agent, an antiemetic, a hematopoietic growth factor, a colony stimulating factor, a biological response modifier, and a bisphosphonate if payment for the drug or biological as an outpatient hospital service was being made on August 1, 2000.

(3) Radiopharmaceutical drugs and biological products. A radiopharmaceutical drug or biological product used in diagnostic, monitoring, and therapeutic nuclear medicine services if payment for the drug or biological as an outpatient hospital service was being made on August 1, 2000.

(4) Other drugs and biologicals. A drug or biological that meets the following conditions:

(i) It was first payable as an outpatient hospital service after December 31, 1996.

(ii) CMS has determined the cost of the drug or biological is not insignificant in relation to the amount payable for the applicable APC (as calculated under § 419.32(c)) as defined in paragraph (b) of this section.

(b) Cost. CMS determines the cost of a drug or biological to be not insignificant if it meets the following requirements:

(1) Services furnished before January 1, 2003. The expected reasonable cost of a drug or biological must exceed 10 percent of the applicable APC payment amount for the service related to the drug or biological.

(2) Services furnished after December 31, 2002. CMS considers the average cost of a new drug or biological to be not insignificant if it meets the following conditions:

(i) The estimated average reasonable cost of the drug or biological in the category exceeds 10 percent of the applicable APC payment amount for the service related to the drug or biological.

(ii) The estimated average reasonable cost of the drug or biological exceeds the cost of the drug or biological portion of the APC payment amount for the related service by at least 25 percent.

(iii) The difference between the estimated reasonable cost of the drug or biological and the estimated portion of the APC payment amount for the drug or biological exceeds 10 percent of the APC payment amount for the related service.

(c) Limited period of payment. CMS limits the eligibility for a pass-through payment under this section to a period of at least 2 years, but not more than 3 years, that begins as follows:

(1) For a drug or biological described in paragraphs (a)(1) through (a)(3) of this section -- August 1, 2000.

(2) For a drug or biological described in paragraph (a)(4) of this section -- the date that CMS makes its first pass-through payment for the drug or biological.

(d) Amount of pass-through payment. (1) Subject to any reduction determined under § 419.62(b), the pass-through payment for a drug or biological as specified in section 1842(o)(1)(A) and (o)(1)(D)(i) of the Act is 95 percent of the average wholesale price of the drug or biological minus the portion of the APC payment CMS determines is associated with the drug or biological.

(2) Subject to any reduction determined under § 419.62(b), the pass-through payment for a drug or biological as specified in section 1842(o)(1)(B) and (o)(1)(E)(i) of the act is 85 percent of the average wholesale price, determined as of April 1, 2003, of the drug or biological minus the portion of the APC payment CMS determines is associated with the drug or biological.

Effective January 1, 2005, Section 419.64 is amended by revising paragraph (d) to read as follows:

(d) *Amount of pass-through payment.* Subject to any reduction determined under § 419.62(b), the pass-through payment for a drug or biological equals the amount determined under section 1842(o) of the Social Security Act, minus the portion of the APC payment amount that CMS determines is associated with the drug or biological.

Effective January 1, 2010, Section 419.64 is amended by adding new paragraphs (a)(4)(iii) and (a)(4)(iv), to read as follows:

(a) * * *

(4) * * *

(iii) A biological that is not surgically implanted or inserted into the body.

(iv) A biological that is surgically implanted or inserted into the body, for which pass-through payment as a biological is made on or before December 31, 2009.

42 C.F.R. § 419.66

Transitional pass-through payments: medical devices.

(a) General rule. CMS makes a pass-through payment for a medical device that meets the requirements in paragraph (b) of this section and that is described by a category of devices established by CMS under the criteria in paragraph (c) of this section.

(b) Eligibility. A medical device must meet the following requirements:

(1) If required by the FDA, the device must have received FDA approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA in accordance with §§ 405.203 through 405.207 and 405.211 through 405.215 of this chapter) or another appropriate FDA exemption.

(2) The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part (as required by section 1862(a)(1)(A) of the Act).

(3) The device is an integral and subordinate part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted whether or not it remains with the patient when the patient is released from the hospital.

(4) The device is not any of the following:

(i) Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1).

(ii) A material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than radiological site marker).

(iii) A material that may be used to replace human skin (for example, a biological or synthetic material).

(c) Criteria for establishing device categories. CMS uses the following criteria to establish a category of devices under this section:

(1) CMS determines that a device to be included in the category is not described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996.

(2) CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment.

(3) Except for medical devices identified in paragraph (e) of this section, CMS determines the cost of the device is not insignificant as described in paragraph (d) of this section.

(d) Cost criteria. CMS considers the average cost of a category of devices to be not insignificant if it meets the following conditions:

(1) The estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices.

(2) The estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent.

(3) The difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service.

(e) Devices exempt from cost criteria. The following medical devices are not subject to the cost requirements described in paragraph (d) of this section, if payment for the device was being made as an outpatient service on August 1, 2000:

(1) A device of brachytherapy.

(2) A device of temperature-monitored cryoablation.

(f) Identifying a category for a device. A device is described by a category, if it meets the following conditions:

(1) Matches the long descriptor of the category code established by CMS.

(2) Conforms to guidance issued by CMS relating to the definition of terms and other information in conjunction with the category descriptors and codes.

(g) Limited period of payment for devices. CMS limits the eligibility for a pass-through payment established under this section to a period of at least 2 years, but not more than 3 years beginning on the date that CMS establishes a category of devices.

(h) Amount of pass-through payment. Subject to any reduction determined under § 419.62(b), the pass-through payment for a device is the hospital's charge for the device, adjusted to the actual cost for the device, minus the amount included in the APC payment amount for the device.

Effective January 1, 2006, Section 419.66 is amended by revising paragraph (c)(1) to read as follows:

*(c) Criteria for establishing device categories. * * **

(1) CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996.

Effective January 1, 2010, Section 419.66 is amended by revising paragraph (b)(4)(iii) to read as follows:

(b) * * *

(4) * * *

(iii) A material that may be used to replace human skin (for example, a biological skin replacement material or synthetic skin replacement material).