

(iii) They are 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. Some investigational devices are refinements of existing technologies or replications of existing technologies and may be considered reasonable and necessary. If such devices have received an FDA investigational device exemption (IDE) and are classified by the FDA as Category B devices in accordance with sections §§ 405.203 to 405.215 of this chapter, excluding § 405.209, they will be considered for coverage under the hospital outpatient prospective payment system.

(iv) They are an integral and subordinate part of the procedure performed, are used for one patient only, are single use, come in contact with human tissue, and are surgically implanted or inserted whether or not they remain with the patient when the patient is released from the hospital outpatient department.

(v) The associated cost is not insignificant, as determined under paragraph (e)(1)(iv) of this section, in relation to the APC payment for the service in which the related medical device is packaged.

(vi) They are not equipment, instruments, apparatuses, implements, or such items for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (HCFA Pub. 15-1).

(vii) They are not materials and supplies such as sutures, customized surgical kits, or clips, other than radiological site markers, furnished incident to a service or procedure. Supplies include pharmacological imaging and stressing agents other than radiopharmaceutical (for which transitional pass-through payment is authorized under section 1833(t)(6)(A) of the Act).

(viii) They are not materials such as biologicals or synthetics that may be used to replace human skin.

(5) *Limit on aggregate annual adjustment*—(i) *General rule.* The total of the additional payments made under this paragraph for hospital outpatient services furnished in a year, as estimated

by HCFA before the beginning of the year, may not exceed the applicable percentage specified in paragraph (e)(4)(ii) of this section of the total program payments estimated to be made under this section 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 (e)(4)(i) of this section, the term “applicable percentage” means—

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

(B) For 2004 and thereafter, a percentage specified by HCFA up to (but not to exceed) 2.0 percent.

(iii) *Uniform prospective reduction if aggregate limit projected to be exceeded.* If HCFA estimates before the beginning of a year that the amount of the additional payments under this paragraph (e) for the year (or portion thereof) as determined under paragraph (e)(4)(i) of this section without regard to this paragraph (e)(4)(iii) would exceed the limit established under this paragraph (e)(4)(iii), HCFA reduces pro rata the amount of each of the additional payments under this paragraph for that year (or portion thereof) in order to ensure that the aggregate additional payments under this paragraph (as so estimated) do not exceed the limit.

(f) *Budget neutrality.* Outlier adjustments under paragraph (d) of this section and transitional pass-through payments under paragraph (e) of this section are established in a budget-neutral manner.

[65 FR 18542, Apr. 7, 2000, as amended at 65 FR 47677, Aug. 3, 2000]

§ 419.44 Payment reductions for surgical procedures.

(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

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(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.

Subpart E—Updates

§ 419.50 Annual review.

(a) *General rule.* Not less often than annually, HCFA 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.* HCFA will consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise HCFA 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.* HCFA conducts the first annual review under paragraph (a) of this section in 2001 for payments made in 2002.

Subpart F—Limitations on Review

§ 419.60 Limitations on administrative and judicial review.

There can be no administrative or judicial review under sections 1869 and 1878 of the Act or otherwise of the following:

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(a) The development of the APC system, including—

(1) Establishment of the groups and relative payment weights;

(2) Wage adjustment factors;

(3) Other adjustments; and

(4) Methods for controlling unnecessary increases in volume.

(b) The calculation of base amounts described in section 1833(t)(3) of the Act.

(c) Periodic adjustments described in section 1833(t)(9) of the Act.

(d) The establishment of a separate conversion factor for hospitals described in section 1886(d)(1)(B)(v) of the Act.

(e) The determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under § 419.43(d) or the determination of insignificance of cost, the duration of the additional payments (consistent with § 419.43(e)), the portion of the Medicare hospital outpatient fee schedule amount associated with particular devices, drugs, or biologicals, and the application of any pro rata reduction under § 419.43(e).

Subpart G—Transitional Corridors

§ 419.70 Transitional adjustment to limit decline in payment.

(a) *Before 2002.* Except as provided in paragraph (d) of this section, for covered hospital outpatient services furnished before January 1, 2002, for which the prospective payment system amount (as defined in paragraph (e) of this section) is—

(1) At least 90 percent, but less than 100 percent, of the pre-BBA amount (as defined in paragraph (f) of this section), the amount of payment under this part is increased by 80 percent of the amount of this difference;

(2) At least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this part is increased by the amount by which the product of 0.71 and the pre-BBA amount exceeds the product of 0.70 and the prospective payment system amount;

(3) At least 70 percent, but less than 80 percent, of the pre-BBA amount, the amount of payment under this part is increased by the amount by which the