

## § 419.42

(3) Determines the value equal to 20 percent of the wage-neutralized 1996 median charge for each APC group and multiplies that value by an actuarial projection of increases in charges for hospital outpatient department services during the period 1996 to 1999. The result is the unadjusted beneficiary coinsurance amount for the APC group.

(b) HCFA calculates annually the program payment percentage for every APC group on the basis of each group's unadjusted coinsurance amount and its payment rate after the payment rate is adjusted in accordance with § 419.32.

(c) To determine payment amounts due for a service paid under the hospital outpatient prospective payment system, HCFA makes the following calculations:

(1) Makes the wage index adjustment in accordance with § 419.43.

(2) Subtracts the amount of the applicable Part B deductible provided under § 410.160 of this chapter.

(3) Multiplies the remainder by the program payment percentage for the group to determine the preliminary Medicare program payment amount.

(4) Subtracts the program payment amount from the amount determined in paragraph (c)(2) of this section to determine the coinsurance amount.

(i) The coinsurance amount for an APC cannot exceed the amount of the inpatient hospital deductible established under section 1813(b) of the Act for that year.

(ii) The coinsurance amount is computed as if the adjustments under § 419.43(d) and (e) (and any adjustment made under § 419.43(f) in relation to these adjustments) had not been paid.

(5) Adds the amount by which the coinsurance amount would have exceeded the inpatient hospital deductible for that year to the preliminary Medicare program payment amount determined in paragraph (c)(3) of this section to determine the final Medicare program payment amount.

### § 419.42 Hospital election to reduce coinsurance.

(a) A hospital may elect to reduce coinsurance for any or all APC groups on a calendar year basis. A hospital may *not* elect to reduce copayment for

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some, but not all, services within the same group.

(b) A hospital must notify its fiscal intermediary of its election to reduce coinsurance no later than—

(1) June 1, 2000, for coinsurance elections for the period July 1, 2000 through December 31, 2000; or

(2) December 1 preceding the beginning of each subsequent calendar year.

(c) The hospital's election must be properly documented. It must specifically identify the APCs to which it applies and the coinsurance amount (within the limits identified below) that the hospital has selected for each group.

(d) The election of reduced coinsurance remains in effect unchanged during the year for which the election was made.

(e) In electing reduced coinsurance, a hospital may elect a level that is less than that year's wage-adjusted coinsurance amount for the group but not less than 20 percent of the APC payment rate as determined in § 419.32.

(f) The hospital may advertise and otherwise disseminate information concerning the reduced level of coinsurance that it has elected. All advertisements and information furnished to Medicare beneficiaries must specify that the coinsurance reductions advertised apply only to the specified services of that hospital and that coinsurance reductions are available only for hospitals that choose to reduce coinsurance for hospital outpatient services and are not allowed in any other ambulatory settings or physician offices.

### § 419.43 Adjustments to national program payment and beneficiary coinsurance amounts.

(a) *General rule.* HCFA 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 coinsurance 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.* HCFA 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.* HCFA 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, HCFA provides for an additional payment for each hospital outpatient service (or group of services) 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 HCFA, a fixed dollar amount.

(2) *Amount of adjustment.* The amount of the additional payment under paragraph (d)(1) of this section is determined by HCFA 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 HCFA 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 HCFA 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, HCFA 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 HCFA), rather than for specific departments within the hospital.

(e) *Transitional pass-through for additional costs of innovative medical devices, drugs, and biologicals—(1) General rule.* HCFA provides for an additional payment under this paragraph for any of the following that are provided as part of a hospital outpatient service (or group of services):

(i) *Current orphan drugs.* A drug or biological that is used for a rare disease or condition with respect to which the drug or biological 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 under this part was being made on the first date that the system under this part is implemented.

(ii) *Current cancer therapy drugs and biologicals and brachytherapy.* 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, a bisphosphonate, and a device of brachytherapy, if payment for the drug, biological, or device as an outpatient hospital service under this part was being made on the first date that

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the system under this part is implemented.

(iii) *Current radiopharmaceutical drugs and biological products.* A radiopharmaceutical drug or biological product used in diagnostic, monitoring, and therapeutic nuclear medicine procedures if payment for the drug or biological as an outpatient hospital service under this part was being made on the first date that the system under this part is implemented.

(iv) *New medical devices, drugs, and biologicals.* A medical device, drug, or biological not described in paragraph (e)(1)(i), (e)(1)(ii), or (e)(1)(iii) of this section if—

(A) Payment for the device, drug, or biological as an outpatient hospital service under this part was not being made as of December 31, 1996; and

(B) The cost of the device, drug, or biological is not insignificant (as defined in paragraph (e)(1)(iv)(C) and (D) of this section) in relation to the hospital outpatient fee schedule amount (as calculated under §419.32(c)) payable for the service (or group of services) involved.

(C) In the case of a new device, drug, or biological for which a transitional pass-through payment is first made before January 1, 2003, the cost of the device, drug, or biological is considered not insignificant if its expected reasonable cost exceeds 10 percent of the applicable fee schedule amount for the associated service.

(D) In the case of a new device, drug, or biological for which a transitional pass-through payment is first made on or after January 1, 2003, the cost of the device, drug, or biological is considered not insignificant if it meets all of the following thresholds:

(1) Its expected reasonable cost exceeds 10 percent of the applicable fee schedule amount for the associated service.

(2) The expected reasonable cost of the new drug, biological, or device must exceed the current portion of the fee schedule amount determined to be associated with the drug, biological, or device by 25 percent.

(3) The difference between the expected reasonable cost of the item and the portion of the hospital outpatient fee schedule amount determined to be

associated with the item exceeds 10 percent of the applicable hospital outpatient fee schedule amount.

(2) *Limited period of payment.* The payment under this paragraph (e) with respect to a medical device, drug, or biological applies during a period of at least 2 years, but not more than 3 years, that begins—

(i) On the first date this section is implemented in the case of a drug, biological, or device described in paragraphs (e)(2)(i), (e)(2)(ii), or (e)(2)(iii) of this section and in the case of a device, drug, or biological described in paragraph (e)(1)(iv) of this section and for which payment under this part is made as an outpatient hospital service before the first date; or

(ii) In the case of a device, drug, or biological described in paragraph (e)(1)(iv) of this section not described in paragraph (e)(2)(i) of this section, on the first date on which payment is made under this part for the device, drug, or biological as an outpatient hospital service.

(3) *Amount of additional payment.* Subject to paragraph (e)(4)(iii) of this section, the amount of the payment under this paragraph is—

(i) In the case of a drug or biological, the amount by which the amount determined under section 1842(o) of the Act for the drug or biological exceeds the portion of the otherwise applicable Medicare hospital outpatient fee schedule amount that HCFA determines is associated with the drug or biological; or

(ii) In the case of a medical device, the amount by which the hospital's charges for the device, adjusted to cost, exceeds the portion of the otherwise applicable Medicare hospital outpatient fee schedule amount that HCFA determines is associated with the device.

(4) *Criteria to define new or innovative medical devices eligible for pass-through payments.* HCFA makes pass-through payment for new or innovative medical devices that meet all of the following criteria:

(i) They were not recognized for payment as a hospital outpatient service prior to 1997.

(ii) They have been approved/cleared for use by the FDA.

(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