

The drug copayment schedule must be reviewed for reasonableness and approved by the intermediary before it is used.

(b) *Respite care.* (1) The amount of coinsurance for each respite care day is equal to 5 percent of the payment made by HCFA for a respite care day.

(2) The amount of the individual's coinsurance liability for respite care during a hospice coinsurance period may not exceed the inpatient hospital deductible applicable for the year in which the hospice coinsurance period began.

(3) The individual hospice coinsurance period—

(i) Begins on the first day an election filed in accordance with §418.24 is in effect for the beneficiary; and

(ii) Ends with the close of the first period of 14 consecutive days on each of which an election is not in effect for the beneficiary.

§418.402 Individual liability for services that are not considered hospice care.

Medicare payment to the hospice discharges an individual's liability for payment for all services, other than the hospice coinsurance amounts described in §418.400, that are considered covered hospice care (as described in §418.202). The individual is liable for the Medicare deductibles and coinsurance payments and for the difference between the reasonable and actual charge on unassigned claims on other covered services that are not considered hospice care. Examples of services not considered hospice care include: Services furnished before or after a hospice election period; services of the individual's attending physician, if the attending physician is not an employee of or working under an arrangement with the hospice; or Medicare services received for the treatment of an illness or injury not related to the individual's terminal condition.

§418.405 Effect of coinsurance liability on Medicare payment.

The Medicare payment rates established by HCFA in accordance with §418.306 are not reduced when the individual is liable for coinsurance payments. Instead, when establishing the

payment rates, HCFA offsets the estimated cost of services by the estimate of average coinsurance amounts hospices collect.

[56 FR 26919, June 12, 1991]

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

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AUTHORITY: Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395l(t), and 1395hh).

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Subpart A—General Provisions**§ 419.1 Basis and scope.**

(a) *Basis.* This part implements section 1833(t) of the Act by establishing a prospective payment system for services furnished on or after July 1, 2000 by hospital outpatient departments to Medicare beneficiaries who are registered on hospital records as outpatients.

(b) *Scope.* This subpart describes the basis of payment for outpatient hospital services under the prospective payment system. Subpart B sets forth the categories of hospitals and services that are subject to the outpatient hospital prospective payment system and those categories of hospitals and services that are excluded from the outpatient hospital prospective payment system. Subpart C sets forth the basic methodology by which prospective payment rates for hospital outpatient services are determined. Subpart D describes Medicare payment amounts, beneficiary copayment amounts, and methods of payment to hospitals under the hospital outpatient prospective payment system. Subpart E describes how the hospital outpatient prospective payment system may be updated. Subpart F describes limitations on administrative and judicial review. Subpart G describes the transitional payment adjustments that are made before 2004 to limit declines in payment for outpatient services.

§ 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 Health Care Financing Administration 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 rates:

(1) Medical education costs for approved nursing and allied health education programs.

(2) Corneal tissue acquisition costs incurred by hospitals that are paid for on a reasonable cost basis.

(3) Costs for services listed in § 419.22.

Subpart B—Categories of Hospitals and Services Subject to and Excluded From the Hospital Outpatient Prospective Payment System

§ 419.20 Hospitals subject to the hospital outpatient prospective payment system.

(a) *Applicability.* The hospital outpatient prospective payment system is applicable to any hospital participating in the Medicare program, except those specified in paragraph (b) of this section, for services furnished on or after July 1, 2000.

(b) *Hospitals excluded from the outpatient prospective payment system.* (1) Those services furnished by Maryland hospitals that are paid under a cost containment waiver in accordance with section 1814(b)(3) of the Act are excluded from the hospital outpatient prospective payment system.

(2) Critical access hospitals (CAHs) are excluded from the hospital outpatient prospective payment system.

§ 419.21 Hospital outpatient services subject to the outpatient prospective payment system.

Except for services described in § 419.22, effective for services furnished on or after July 1, 2000, payment is made under the hospital outpatient prospective payment system for the following:

(a) Medicare Part B services furnished to hospital outpatients designated by the Secretary under this part.

(b) Services designated by the Secretary that are covered under Medicare Part B when furnished to hospital inpatients who are either not entitled to benefits under Part A or who have exhausted their Part A benefits but are entitled to benefits under Part B of the program.

(c) Partial hospitalization services furnished by community mental health centers (CMHCs).

(d) The following medical and other health services furnished by a comprehensive outpatient rehabilitation facility (CORF) when they are provided outside the patient's plan (of care); or by a home health agency (HHA) to patients who are not under an HHA plan or treatment; or by a hospice program furnishing services to patients outside the hospice benefit:

(1) Antigens.

(2) Splints and casts.

(3) Pneumococcal vaccine, influenza vaccine, and hepatitis B vaccine.

§ 419.22 Hospital outpatient services excluded from payment under the hospital outpatient prospective payment system.

The following services are not paid for under the hospital outpatient prospective payment system:

(a) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(b) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(c) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(d) Certified nurse-midwife services, as defined in section 1861(gg) of the Act.

(e) Services of qualified psychologists, as defined in section 1861(ii) of the Act.

(f) Services of an anesthetist as defined in § 410.69 of this chapter.

(g) Clinical social worker services as defined in section 1861(hh)(2) of the Act.

(h) Outpatient therapy services described in section 1833(a)(8) of the Act.

(i) Ambulance services, as described in section 1861(v)(1)(U) of the Act, or, if applicable, the fee schedule established under section 1834(l).

(j) Except as provided in § 419.22(b)(11), prosthetic devices, prosthetics, prosthetic supplies, and orthotic devices.

(k) Except as provided in § 419.2(b)(10), durable medical equipment supplied by the hospital for the patient to take home.

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(l) Clinical diagnostic laboratory services.

(m) Services for patients with ESRD that are paid under the ESRD composite rate and drugs and supplies furnished during dialysis but not included in the composite rate.

(n) Services and procedures that the Secretary designates as requiring inpatient care.

(o) Hospital outpatient services furnished to SNF residents (as defined in § 411.15(p) of this chapter) as part of the patient's resident assessment or comprehensive care plan (and thus included under the SNF PPS) that are furnished by the hospital "under arrangements" but billable only by the SNF, regardless of whether or not the patient is in a Part A SNF stay.

(p) Services that are not covered by Medicare by statute.

(q) Services that are not reasonable or necessary for the diagnosis or treatment of an illness or disease.

Subpart C—Basic Methodology for Determining Prospective Payment Rates for Hospital Outpatient Services

§ 419.30 Base expenditure target for calendar year 1999.

(a) HCFA estimates the aggregate amount that would be payable for hospital outpatient services in calendar year 1999 by summing—

(1) The total amounts that would be payable from the Trust Fund for covered hospital outpatient services without regard to the outpatient prospective payment system described in this part; and

(2) The total amounts of coinsurance that would be payable by beneficiaries to hospitals for covered hospital outpatient services without regard to the outpatient prospective payment system described in this part.

(b) The estimated aggregate amount under paragraph (a) of this section is determined as though the deductible required under section 1833(b) of the Act did not apply.

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§ 419.31 Ambulatory payment classification (APC) system and payment weights.

(a) *APC groups.* (1) HCFA classifies outpatient services and procedures that are comparable clinically and in terms of resource use into APC groups. Except as specified in paragraph (a)(2) of this section, items and services within a group are not comparable with respect to the use of resources if the highest median cost for an item or service within the group is more than 2 times greater than the lowest median cost for an item or service within the group.

(2) HCFA may make exceptions to the requirements set forth in paragraph (a)(1) in unusual cases, such as low volume items and services, but may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act.

(3) The payment rate determined for an APC group in accordance with § 419.32, and the copayment amount and program payment amount determined for an APC group in accordance with subpart D of this part, apply to every HCPCS code classified within an APC group.

(b) *APC weighting factors.* (1) Using hospital outpatient claims data from calendar year 1996 and data from the most recent available hospital cost reports, HCFA determines the median costs for the services and procedures within each APC group.

(2) HCFA assigns to each APC group an appropriate weighting factor to reflect the relative median costs for the services within the APC group compared to the median costs for the services in all APC groups.

(c) *Standardizing amounts.* (1) HCFA determines the portion of costs determined in paragraph (b)(1) of this section that is labor-related. This is known as the "labor-related portion" of hospital outpatient costs.

(2) HCFA standardizes the median costs determined in paragraph (b)(1) of this section by adjusting for variations in hospital labor costs across geographic areas.

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

(a) *Conversion factor for 1999.* HCFA 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 years 2000, 2001, and 2002, 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 years 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, HCFA 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.* HCFA adjusts the conversion factor as needed to ensure that updates and adjustments under § 419.50(a) are budget neutral.

Subpart D—Payments to Hospitals

§ 419.40 Payment concepts.

(a) In addition to the payment rate described in § 419.32, for each APC group there is a predetermined beneficiary coinsurance amount as described in § 419.41(a). The Medicare program payment amount for each APC group is calculated by applying the program payment percentage as described in § 419.41(b).

(b) For purposes of this section—

(1) *Coinsurance percentage* is calculated as the difference between the program payment percentage and 100 percent. The coinsurance percentage in any year is thus defined for each APC group as the *greater* of the following: the ratio of the APC group unadjusted copayment amount to the annual APC group payment rate, or 20 percent.

(2) *Program payment percentage* is calculated as the *lower* of the following: the ratio of the APC group payment rate minus the APC group unadjusted coinsurance amount, to the APC group payment rate, or 80 percent.

(3) *Unadjusted coinsurance amount* is calculated as 20 percent of the wage-adjusted national median of charges for services within an APC group furnished during 1996, updated to 1999 using an actuarial projection of charge increases for hospital outpatient department services during the period 1996 to 1999.

(c) *Limitation of coinsurance amount to inpatient hospital deductible amount.* The coinsurance amount for a procedure performed in a year cannot exceed the amount of the inpatient hospital deductible established under section 1813(b) of the Act for that year.

§ 419.41 Calculation of national beneficiary coinsurance amounts and national Medicare program payment amounts.

(a) To calculate the unadjusted coinsurance amount for each APC group, HCFA—

(1) Standardizes 1996 hospital charges for the services within each APC group to offset variations in hospital labor costs across geographic areas;

(2) Identifies the median of the wage-neutralized 1996 charges for each APC group; and

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(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

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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

product of 0.63 and the pre-BBA amount, exceeds the product of 0.60 and the PPS amount; or

(4) Less than 70 percent of the pre-BBA amount, the amount of payment under this part shall be increased by 21 percent of the pre-BBA amount.

(b) *For 2002.* Except as provided in paragraph (d) of this section, for covered hospital outpatient services furnished during 2002, for which the prospective payment system amount is—

(1) At least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this part is increased by 70 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 0.61 and the pre-BBA amount exceeds the product of 0.60 and the prospective payment system amount; or

(3) Less than 80 percent of the pre-BBA amount, the amount of payment under this part is increased by 13 percent of the pre-BBA amount.

(c) *For 2003.* Except as provided in paragraph (d) of this section, for covered hospital outpatient services furnished during 2003, for which the prospective payment system amount is—

(1) At least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this part is increased by 60 percent of the amount of this difference; or

(2) Less than 90 percent of the pre-BBA amount, the amount of payment under this part is increased by 6 percent of the pre-BBA amount.

(d) *Hold harmless provisions—(1) Temporary treatment for small rural hospitals.* For covered hospital outpatient services furnished in a calendar year before January 1, 2004 for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by the amount of that difference if the hospital—

(i) Is located in a rural area as defined in § 412.63(b) of this chapter or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act; and

(ii) Has 100 or fewer beds as defined in § 412.105(b) of this chapter.

(2) *Permanent treatment for cancer hospitals.* In the case of a hospital described in § 412.23(f) of this chapter for which the prospective payment system amount is less than the pre-BBA amount for covered hospital outpatient services, the amount of payment under this part is increased by the amount of this difference.

(e) *Prospective payment system amount defined.* In this paragraph, the term “prospective payment system amount” means, with respect to covered hospital outpatient services, the amount payable under this part for these services (determined without regard to this paragraph or any reduction in coinsurance elected under § 419.42), including amounts payable as copayment under § 419.41, coinsurance under section 1866(a)(2)(A)(ii) of the Act, and the deductible under section 1833(b) of the Act.

(f) *Pre-BBA amount defined—(1) General rule.* In this paragraph, the “pre-BBA amount” means, with respect to covered hospital outpatient services furnished by a hospital or a community mental health center (CMHC) in a year, an amount equal to the product of the reasonable cost of the provider for these services for the portions of the provider’s cost reporting period (or periods) occurring in the year and the base provider outpatient payment-to-cost ratio for the provider (as defined in paragraph (f)(2) of this section).

(2) *Base payment-to-cost-ratio defined.* For purposes of this paragraph, HCFA shall determine these ratios as if the amendments to sections 1833(i)(3)(B)(i)(II) and 1833(n)(1)(B)(i) of the Act made by section 4521 of the BBA, to require that the full amount beneficiaries paid as coinsurance under section 1862(a)(2)(A) of the Act are taken into account in determining Medicare Part B Trust Fund payment to the hospital, were in effect in 1996. The “base payment-to-cost ratio” for a hospital or CMHC means the ratio of—

(i) The provider’s payment under this part for covered outpatient services furnished during the cost reporting period ending in 1996, including any payment for these services through cost-

sharing described in paragraph (e) of this section; and

(ii) The reasonable cost of these services for this period, without applying the cost reductions under section 1861(v)(1)(S) of the Act.

(g) *Interim payments.* HCFA makes payments under this paragraph to hospitals and CMHCs on an interim basis, subject to retrospective adjustments based on settled cost reports.

(h) *No effect on coinsurance.* No payment made under this section affects the unadjusted coinsurance amount or the coinsurance amount described in § 419.41.

(i) *Application without regard to budget neutrality.* The additional payments made under this paragraph—

(1) Are not considered an adjustment under § 419.43(f); and

(2) Are not implemented in a budget neutral manner.

PART 420—PROGRAM INTEGRITY: MEDICARE

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420.410 Establishment of a program to collect suggestions for improving Medicare program efficiency and to reward suggesters for monetary savings.

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 44 FR 31142, May 30, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 420.1 Scope and purpose.

This part sets forth requirements for Medicare providers, intermediaries, and carriers to disclose ownership and control information. It also deals with access to records pertaining to certain contracts entered into by Medicare providers. These rules are aimed at protecting the integrity of the Medicare program. The statutory basis for these requirements is explained in each of the other subparts.

[51 FR 34787, Sept. 30, 1986]

§ 420.3 Other related regulations.

(a) *Appeals procedures.* Part 498 of this chapter sets forth the appeals procedures available to providers whose provider agreements HCFA terminates for failure to comply with the disclosure of information requirements set forth in subpart C of this part.

(b) *Exclusion, termination, or suspension.* Part 1001 of this title sets forth the rules applicable to exclusion, termination, or suspension from the Medicare program because of fraud or abuse or conviction of program-related crimes.

[51 FR 34787, Sept. 30, 1986, as amended at 52 FR 22454, June 12, 1987]

Subpart B—[Reserved]