

1847A(i)(2)(A) of the Act), to calculate the program payment and copayment amounts CMS does the following:

(1) Determines the payment rate for the drug or biological for the quarter established under the methodology described by section 1842(o), section 1847A, or section 1847B of the Act, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of paragraph (14) of section 1833(t) of the Act.

(2) Subtracts from the amount determined under paragraph (d)(1) of this section the amount of the applicable Part B deductible provided under § 410.160 of this chapter.

(3) Multiplies the amount determined under paragraph (d)(1) of this section (less any applicable deductible under paragraph (d)(2) of this section) by 20 percent. This is the beneficiary's copayment amount for the drug or biological.

(4) Subtracts the amount determined under paragraph (d)(3) of this section from the amount determined under paragraph (d)(1) of this section (less any applicable deductible determined under paragraph (d)(2) of this section). This amount is the preliminary program amount.

(5) Adds to the preliminary program amount determined under paragraph (d)(4) of this section the amount by which the copayment amount would have exceeded the inpatient hospital deductible for that year. This amount is the final Medicare program payment amount.

(e) In the case of a rebatable drug (as defined in section 1847A(i)(2)(A) of the Act), except if such drug does not have a copayment amount as a result of application of section 1833(t)(8)(E) of the Act, for which payment is not packaged into payment for a covered OPD service (or group of services) furnished on or after April 1, 2023, and the payment for such drug under the outpatient prospective payment system (OPPS) is the same as the amount for a calendar quarter under section 1847A(i)(3)(A)(ii)(I) of the Act, in lieu of the calculation of the copayment amount and the Medicare program payment amount otherwise applicable under paragraph (d) of this section (other than application of the limita-

tion described in paragraph (c)(4)(i) of this section), the copayment and Medicare program payment amounts determined under §§ 410.152(m) and 489.30(b)(6) of this chapter shall apply.

(f) In the case of a qualifying biosimilar biological product (as defined in § 414.902 of this chapter) that is furnished during the applicable five-year period (as defined in § 414.902 of this chapter) for such product, the payment amount for such product with respect to such period is the amount determined in § 414.904(j)(2) of this chapter.

(g) For dates of service on or after July 1, 2024, the payment amount for a biosimilar biological product (as defined in § 414.902 of this chapter) during the initial period is the amount determined in § 414.904(e)(4)(ii) of this chapter.

[65 FR 18542, Apr. 7, 2000, as amended at 65 FR 67829, Nov. 13, 2000; 66 FR 59923, Nov. 30, 2001; 73 FR 68814, Nov. 18, 2008; 88 FR 82180, Nov. 22, 2023]

§ 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 amounts for 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 copayment 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 copayment amount that is less than that year's wage-adjusted copayment amount for the group but not less than 20 percent of the APC payment rate as determined

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under § 419.32 or, in the case of payments calculated under § 419.43(h), not less than 20 percent of the APC payment rate as determined under § 419.43(h).

(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.

[65 FR 18542, Apr. 7, 2000, as amended at 65 FR 67829, Nov. 13, 2000; 66 FR 59923, Nov. 30, 2001; 73 FR 68814, Nov. 18, 2008]

§ 419.43 Adjustments to national program payment and beneficiary co-payment 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 co-payment 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.* (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.

(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 § 419.66.

(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.

(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 no-

tice 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.

(7) *Community mental health center (CMHC) outlier payment cap.* Outlier payments made to CMHCs for services provided on or after January 1, 2017 are subject to a cap, applied at the individual CMHC level, so that each CMHC's total outlier payments for the calendar year do not exceed 8 percent of that CMHC's total per diem payments for the calendar year. Total per diem payments are total Medicare per diem payments plus the total beneficiary share of those per diem payments.

(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.* 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) *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 or is an essential access community hospital under § 412.109 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.* 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.

(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.

(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 Sec-

retary 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 OPPIs 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.

(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).

(i) *Payment adjustment for certain cancer hospitals—(1) General rule.* CMS provides for a payment adjustment for covered hospital outpatient department services furnished on or after January 1, 2012, by a hospital described in section 1886(d)(1)(B)(v) of the Act.

(2) *Amount of payment adjustment.* The amount of the payment adjustment under paragraph (i)(1) of this section is determined by the Secretary as follows:

(i) If a hospital described in section 1886(d)(1)(B)(v) of the Act has a payment-to-cost ratio (PCR) before the cancer hospital payment adjustment (as determined by the Secretary at cost report settlement) that is less than the weighted average PCR of other hospitals furnishing services under section 1833(t) of the Act (as determined by the Secretary at the time of the applicable CY Hospital Outpatient Prospective Payment System/Ambulatory Surgical Center final rule with comment period) (referred to as the Target PCR), for