

However, a hospital may request payment for day outliers before the medical review required in paragraph (b) of this section.

(b) The QIO must review and approve to the extent required by CMS—

(1) The medical necessity and appropriateness of the admission and outlier services in the context of the entire stay;

(2) The validity of the diagnostic and procedural coding; and

(3) The granting of grace days.

(c) Except as provided in § 412.83, the per diem payment made under paragraph (a) of this section is derived by taking a percentage of the average per diem payment for the applicable DRG, as calculated by dividing the Federal prospective payment rate for inpatient operating costs and inpatient capital-related costs determined under subpart D of this part, by the arithmetic mean length of stay for that DRG. CMS issues the applicable percentage of the average per diem payment in the annual publication of the prospective payment rates in accordance with § 412.8(b).

(d) Any days in a covered stay identified as noncovered reduce the number of days reimbursed at the day outlier rate but not to exceed the number of days that occur after the day outlier threshold.

[50 FR 12741, Mar. 29, 1985, as amended at 50 FR 15326, Apr. 17, 1985; 50 FR 35689, Sept. 3, 1985; 53 FR 38529, Sept. 30, 1988; 57 FR 39822, Sept. 1, 1992; 59 FR 45398, Sept. 1, 1994; 62 FR 46028, Aug. 29, 1997; 85 FR 59020, Sept. 18, 2020]

**§ 412.84 Payment for extraordinarily high-cost cases (cost outliers).**

(a) A hospital may request its intermediary to make an additional payment for inpatient hospital services that meet the criteria established in accordance with § 412.80(a).

(b) The hospital must request additional payment—

(1) With initial submission of the bill; or

(2) Within 60 days of receipt of the intermediary's initial determination.

(c) Except as specified in paragraph (e) of this section, an additional payment for a cost outlier case is made prior to medical review.

(d) As described in paragraph (f) of this section, the QIO reviews a sample of cost outlier cases after payment. The charges for any services identified as noncovered through this review are denied and any outlier payment made for these services are recovered, as appropriate, after a determination as to the provider's liability has been made.

(e) If the QIO finds a pattern of inappropriate utilization by a hospital, all cost outlier cases from that hospital are subject to medical review, and this review may be conducted prior to payment until the QIO determines that appropriate corrective actions have been taken.

(f) The QIO reviews the cost outlier cases, using the medical records and itemized charges, to verify the following:

(1) The admission was medically necessary and appropriate.

(2) Services were medically necessary and delivered in the most appropriate setting.

(3) Services were ordered by the physician, actually furnished, and not duplicatively billed.

(4) The diagnostic and procedural codings are correct.

(g) The intermediary bases the operating and capital costs of the discharge on the billed charges for covered inpatient services adjusted by the cost to charge ratios applicable to operating and capital costs, respectively, as described in paragraph (h) of this section.

(h) For discharges occurring before October 1, 2003, the operating and capital cost-to-charge ratios used to adjust covered charges are computed annually by the intermediary for each hospital based on the latest available settled cost report for that hospital and charge data for the same time period as that covered by the cost report. For discharges occurring before August 8, 2003, statewide cost-to-charge ratios are used in those instances in which a hospital's operating or capital cost-to-charge ratios fall outside reasonable parameters. CMS sets forth the reasonable parameters and the statewide cost-to-charge ratios in each year's annual notice of prospective payment rates published in the FEDERAL REGISTER in accordance with § 412.8(b).

**§ 412.84**

**42 CFR Ch. IV (10–1–23 Edition)**

(i)(1) For discharges occurring on or after August 8, 2003, CMS may specify an alternative to the ratios otherwise applicable under paragraphs (h) or (i)(2) of this section. A hospital may also request that its fiscal intermediary 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 Regional Office.

(2) For discharges occurring on or after October 1, 2003, the operating and capital cost-to-charge ratios applied at the time a claim is processed are 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.

(3) For discharges occurring on or after August 8, 2003, the fiscal intermediary may use a statewide average cost-to-charge ratio if it is unable to determine an accurate operating or capital cost-to-charge ratio for a hospital in one of the following circumstances:

(i) New hospitals that have not yet submitted their first Medicare cost report. (For this purpose, 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.)

(ii) Hospitals whose operating or capital 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 § 412.8(b).

(iii) Other hospitals for whom the fiscal intermediary obtains accurate data with which to calculate either an operating or capital cost-to-charge ratio (or both) are not available.

(4) For discharges occurring on or after August 8, 2003, any reconciliation of outlier payments will be based on operating and capital cost-to-charge ratios 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 discharge is settled.

(j) If any of the services are determined to be noncovered, the charges

for these services will be deducted from the requested amount of reimbursement but not to exceed the amount claimed above the cost outlier threshold.

(k) Except as provided in paragraph (l) of this section, the additional amount is derived by first taking 80 percent of the difference between the hospital's adjusted operating cost for the discharge (as determined under paragraph (g) of this section) and the operating threshold criteria established under § 412.80(a)(1)(ii); 80 percent is also taken of the difference between the hospital's adjusted capital cost for the discharge (as determined under paragraph (g) of this section) and the capital threshold criteria established under § 412.80(a)(1)(ii). The resulting capital amount is then multiplied by the applicable Federal portion of the payment as determined in § 412.340(a) or § 412.344(a).

(l) For discharges occurring on or after April 1, 1988, the additional payment amount for the DRGs related to burn cases, which are identified in the most recent annual notice of prospective payment rates published in accordance with § 412.8(b), is computed under the provisions of paragraph (k) of this section except that the payment is made using 90 percent of the difference between the hospital's adjusted cost for the discharge and the threshold criteria.

(m) Effective for discharges occurring on or after August 8, 2003, at the time of any reconciliation under paragraph (i)(4) of this section, outlier payments may be adjusted to account for the time value of any underpayments or overpayments. Any adjustment will be based upon a widely available index to be established in advance by the Secretary, and will be applied from the midpoint of the cost reporting period to the date of reconciliation.

[50 FR 12741, Mar. 29, 1985, as amended at 50 FR 35689, Sept. 3, 1985; 51 FR 31496, Sept. 3, 1986; 53 FR 38529, Sept. 30, 1988; 54 FR 36494, Sept. 1, 1989; 55 FR 15174, Apr. 20, 1990; 56 FR 43448, Aug. 30, 1991; 57 FR 39823, Sept. 1, 1992; 59 FR 45398, Sept. 1, 1994; 62 FR 46028, Aug. 29, 1997; 68 FR 34515, June 9, 2003; 71 FR 48138, Aug. 18, 2006]

**Centers for Medicare & Medicaid Services, HHS**

**§ 412.87**

PAYMENT ADJUSTMENT FOR CERTAIN CLINICAL TRIAL CASES AND EXPANDED ACCESS USE IMMUNOTHERAPY

**§ 412.85 Payment adjustment for certain clinical trial and expanded access use immunotherapy cases.**

(a) *General rule.* For discharges occurring on or after October 1, 2020, the amount of payment for a discharge described in paragraph (b) of this section is adjusted as described in paragraph (c) of this section.

(b) *Discharges subject to payment adjustment.* Payment is adjusted in accordance with paragraph (c) of this section for discharges assigned to MS-DRG 018 involving expanded access use of immunotherapy, or that are part of an applicable clinical trial as determined by CMS based on the reporting of a diagnosis code indicating the encounter is part of a clinical research program on the claim for the discharge.

(c) *Adjustment.* The DRG weighting factor determined under § 412.60(b) is adjusted by a factor that reflects the average cost for cases to be assigned to MS-DRG 018 that involve expanded access use of immunotherapy, or are part of an applicable clinical trial, to the average cost for cases to be assigned to MS-DRG 018 that do not involve expanded access use of immunotherapy and are not part of an applicable clinical trial.

[85 FR 59020, Sept. 18, 2020]

**§ 412.83 Payment for extraordinarily high-cost day outliers.**

For discharges occurring before October 1, 1997, if a discharge that qualifies for an additional payment under the provisions of § 412.82 has charges adjusted to costs that exceed the cost outlier threshold criteria for an extraordinarily high-cost case as set forth in § 412.80(a)(1)(ii), the additional payment made for the discharge is the greater of—

- (a) The applicable per diem payment computed under § 412.82 (c) or (d); or
- (b) The payment that would be made under § 412.84 (i) or (j) if the case had

not met the day outlier criteria threshold set forth in § 412.80(a)(1)(i).

[53 FR 38529, Sept. 30, 1988, as amended at 62 FR 46028, Aug. 29, 1997. Redesignated at 85 FR 59020, Sept. 18, 2020]

**412.86 [Reserved]**

ADDITIONAL SPECIAL PAYMENT FOR CERTAIN NEW TECHNOLOGY

**§ 412.87 Additional payment for new medical services and technologies: General provisions.**

(a) *Basis.* Sections 412.87 and 412.88 implement sections 1886(d)(5)(K) and 1886(d)(5)(L) of the Act, which authorize the Secretary to establish a mechanism to recognize the costs of new medical services and technologies under the hospital inpatient prospective payment system.

(b) *Eligibility criteria.* For discharges occurring on or after October 1, 2001, CMS provides for additional payments (as specified in § 412.88) beyond the standard DRG payments and outlier payments to a hospital for discharges involving covered inpatient hospital services that are new medical services and technologies, if the following conditions are met:

(1) A new medical service or technology represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

(i) The totality of the circumstances is considered when making a determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

(ii) A determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries means one of the following:

- (A) The new medical service or technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.
- (B) The new medical service or technology offers the ability to diagnose a