

weighting factor to determine the hospital-specific base payment amount (target amount) for a particular covered discharge.

(f) *Notice of hospital-specific rate.* The intermediary furnishes the MDH a notice of its hospital-specific rate which contains a statement of the hospital's Medicare Part A allowable inpatient operating costs, number of Medicare discharges, and case-mix index adjustment factor used to determine the hospital's cost per discharge for the Federal fiscal year 2002 base period.

(g) *Right to administrative and judicial review.* An intermediary's determination of the hospital-specific rate for a hospital is subject to administrative and judicial review. Review is available to an MDH upon receipt of the notice of the hospital-specific rate. The notice is treated as a final intermediary determination of the amount of program reimbursement for purposes of subpart R of part 405 of this chapter, governing provider reimbursement determinations and appeals.

(h) *Modification of hospital-specific rate.* (1) The intermediary recalculates the hospital-specific rate to reflect the following:

(i) Any modifications that are determined as a result of administrative or judicial review of the hospital-specific rate determinations; or

(ii) Any additional costs that are recognized as allowable costs for the MDH's base period as a result of administrative or judicial review of the base-period notice of amount of program reimbursement.

(2) With respect to either the hospital-specific rate determination or the amount of program reimbursement determination, the actions taken on administrative or judicial review that provide a basis for recalculations of the hospital-specific rate include the following:

(i) A reopening and revision of the MDH's base-period notice of amount of program reimbursement under §§ 405.1885 through 405.1889 of this chapter.

(ii) A prehearing order or finding issued during the provider payment appeals process by the appropriate reviewing authority under § 405.1821 or § 405.1853 of this chapter that resolved a

matter at issue in the MDH's base-period notice of amount of program reimbursement.

(iii) An affirmation, modification, or reversal of a Provider Reimbursement Review Board decision by the Administrator of CMS under § 405.1875 of this chapter that resolved a matter at issue in the hospital's base-period notice of amount of program reimbursement.

(iv) An administrative or judicial review decision under § 405.1831, § 405.1871, or § 405.1877 of this chapter that is final and no longer subject to review under applicable law or regulations by a higher reviewing authority, and that resolved a matter at issue in the hospital's base-period notice of amount of program reimbursement.

(v) A final, nonappealable court judgment relating to the base-period costs.

(3) The adjustments to the hospital-specific rate made under paragraphs (h)(1) and (2) of this section are effective retroactively to the time of the intermediary's initial determination of the rate.

(i) *Maintaining budget neutrality.* CMS makes an adjustment to the hospital-specific rate to ensure that changes to the DRG classifications and recalibrations of the DRG relative weights are made in a manner so that aggregate payments to section 1886(d) hospitals are not affected.

[71 FR 48137, Aug. 18, 2006, as amended at 75 FR 50414, Aug. 16, 2010]

### **Subpart F—Payments for Outlier Cases, Special Treatment Payment for New Technology, and Payment Adjustment for Certain Replaced Devices**

#### **PAYMENT FOR OUTLIER CASES**

#### **§ 412.80 Outlier cases: General provisions.**

(a) *Basic rule*—(1) *Discharges occurring on or after October 1, 1994 and before October 1, 1997.* For discharges occurring on or after October 1, 1994, and before October 1, 1997, except as provided in paragraph (b) of this section concerning transferring hospitals, CMS provides for additional payment, beyond standard DRG payments, to a hospital for covered inpatient hospital

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services furnished to a Medicare beneficiary if either of the following conditions is met:

(i) The beneficiary's length-of-stay (including days at the SNF level of care if a SNF bed is not available in the area) exceeds the mean length-of-stay for the applicable DRG by the lesser of the following:

(A) A fixed number of days, as specified by CMS; or

(B) A fixed number of standard deviations, as specified by CMS.

(ii) The beneficiary's length-of-stay does not exceed criteria established under paragraph (a)(1)(i) of this section, but the hospital's charges for covered services furnished to the beneficiary, adjusted to operating costs and capital costs by applying cost-to-charge ratios as described in § 412.84(h), exceed the DRG payment for the case plus a fixed dollar amount (adjusted for geographic variation in costs) as specified by CMS.

(2) *Discharges occurring on or after October 1, 1997 and before October 1, 2001.* For discharges occurring on or after October 1, 1997 and before October 1, 2001, except as provided in paragraph (b) of this section concerning transfers, CMS provides for additional payment, beyond standard DRG payments, to a hospital for covered inpatient hospital services furnished to a Medicare beneficiary if the hospital's charges for covered services, adjusted to operating costs and capital costs by applying cost-to-charge ratios, as described in § 412.84(h), exceed the DRG payment for the case, payments for indirect costs of graduate medical education (§ 412.105), and payments for serving disproportionate share of low-income patients (§ 412.106), plus a fixed dollar amount (adjusted for geographic variation in costs) as specified by CMS.

(3) *Discharges occurring on or after October 1, 2001.* For discharges occurring on or after October 1, 2001, except as provided in paragraph (b) of this section concerning transfers, CMS provides for additional payment, beyond standard DRG payments and beyond additional payments for new medical services or technology specified in §§ 412.87 and 412.88, to a hospital for covered inpatient hospital services furnished to a Medicare beneficiary if the

hospital's charges for covered services, adjusted to operating costs and capital costs by applying cost-to-charge ratios as described in § 412.84(h), exceed the DRG payment for the case (plus payments for indirect costs of graduate medical education (§ 412.105), payments for serving a disproportionate share of low-income patients (§ 412.106), and additional payments for new medical services or technologies) plus a fixed dollar amount (adjusted for geographic variation in costs) as specified by CMS.

(b) *Outlier cases in transferring hospitals.* CMS provides cost outlier payments to a transferring hospital for cases paid in accordance with § 412.4(f), if the hospital's charges for covered services furnished to the beneficiary, adjusted to costs by applying cost-to-charge ratios as described in § 412.84(h), exceed the DRG payment for the case plus a fixed dollar amount (adjusted for geographic variation in costs) as specified by CMS, divided by the geometric mean length of stay for the DRG, and multiplied by an applicable factor determined as follows:

(1) For transfer cases paid in accordance with § 412.4(f)(1), the applicable factor is equal to the length of stay plus 1 day.

(2) For transfer cases paid in accordance with § 412.4(f)(2), the applicable factor is equal to 0.5 plus the product of the length of stay plus 1 day multiplied by 0.5.

(c) *Publication and revision of outlier criteria.* CMS will issue threshold criteria for determining outlier payment in the annual notice of the prospective payment rates published in accordance with § 412.8(b).

[62 FR 46028, Aug. 29, 1997, as amended at 63 FR 41003, July 31, 1998; 66 FR 46924, Sept. 7, 2001; 67 FR 50111, Aug. 1, 2002]

### § 412.82 Payment for extended length-of-stay cases (day outliers).

(a) For discharges occurring before October 1, 1997, if the hospital stay reflected by a discharge includes covered days of care beyond the applicable threshold criterion, the intermediary will make an additional payment, on a per diem basis, to the discharging hospital for those days. A special request or submission by the hospital is not necessary to initiate this payment.

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).

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(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]

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## § 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