

§ 412.84, Medicare will not pay any additional amount beyond the DRG payment plus—

(i) 65 percent of the estimated costs of the new medical service or technology;

(ii) For a medical product designated by FDA as a Qualified Infectious Disease Product, 75 percent of the estimated costs of the new medical service or technology; or

(iii) For discharges occurring on or after October 1, 2020, for a product approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs, 75 percent of the estimated costs of the new medical service or technology.

[66 FR 46924, Sept. 7, 2001, as amended at 67 FR 50111, Aug. 1, 2002; 69 FR 49244, Aug. 11, 2004; 72 FR 47411, Aug. 22, 2007; 84 FR 42612, Aug. 16, 2019; 85 FR 59021, Sept. 18, 2020]

#### PAYMENT ADJUSTMENT FOR CERTAIN REPLACED DEVICES

#### § 412.89 Payment adjustment for certain replaced devices.

(a) *General rule.* For discharges occurring on or after October 1, 2007, the amount of payment for a discharge described in paragraph (b) of this section is reduced when—

(1) A device is replaced without cost to the hospital;

(2) The provider received full credit for the cost of a device; or

(3) The provider receives a credit equal to 50 percent or more of the cost of the device.

(b) *Discharges subject to payment adjustment.* (1) Payment is reduced in accordance with paragraph (a) of this section only if the implantation of the device determines the DRG assignment.

(2) CMS lists the DRGs that qualify under paragraph (b)(1) of this section in the annual final rule for the hospital inpatient prospective payment system.

(c) *Amount of reduction.* (1) For a device provided to the hospital without cost, the cost of the device is subtracted from the DRG payment.

[72 FR 47411, Aug. 22, 2007]

#### Subpart G—Special Treatment of Certain Facilities Under the Prospective Payment System for Inpatient Operating Costs

#### § 412.90 General rules.

(a) *Sole community hospitals.* CMS may adjust the prospective payment rates for inpatient operating costs determined under subpart D or E of this part if a hospital, by reason of factors such as isolated location, weather conditions, travel conditions, or absence of other hospitals, is the sole source of inpatient hospital services reasonably available in a geographic area to Medicare beneficiaries. If a hospital meets the criteria for such an exception under § 412.92(a), its prospective payment rates for inpatient operating costs are determined under § 412.92(d).

(b) *Referral center.* CMS may adjust the prospective payment rates for inpatient operating costs determined under subpart D or E of this part if a hospital acts as a referral center for patients transferred from other hospitals. Criteria for identifying such referral centers are set forth in § 412.96.

(c) [Reserved]

(d) *Kidney acquisition costs incurred by hospitals with approved kidney transplant programs.* CMS pays for kidney acquisition costs incurred by kidney transplant programs on a reasonable cost basis. The criteria for this special payment provision are set forth in § 412.100.

(e) *Hospitals located in areas that are reclassified from urban to rural.* (1) CMS adjusts the rural Federal payment amounts for inpatient operating costs for hospitals located in geographic areas that are reclassified from urban to rural as defined in subpart D of this part. This adjustment is set forth in § 412.102.

(2) CMS establishes a procedure by which certain individual hospitals located in urban areas may apply for reclassification as rural. The criteria for reclassification are set forth in § 412.103.

(f) *Hospitals that have a high percentage of ESRD beneficiary discharges.* CMS makes an additional payment to a hospital if ten percent or more of its total Medicare discharges in a cost reporting period beginning on or after October 1,

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1984 are ESRD beneficiary discharges. In determining ESRD discharges, discharges in DRG Nos. 302, 316, and 317 are excluded. The criteria for this additional payment are set forth in § 412.104.

(g) *Hospitals that incur indirect costs for graduate medical education programs.* CMS makes an additional payment for inpatient operating costs to a hospital for indirect medical education costs attributable to an approved graduate medical education program. The criteria for this additional payment are set forth in § 412.105.

(h) *Hospitals that serve a disproportionate share of low-income patients.* For discharges occurring on or after May 1, 1986, CMS makes an additional payment for inpatient operating costs to hospitals that serve a disproportionate share of low-income patients. The criteria for this additional payment are set forth in § 412.106.

(i) *Hospitals that receive an additional update for FYs 1998 and 1999.* For FYs 1998 and 1999, CMS makes an upward adjustment to the standardized amounts for certain hospitals that do not receive indirect medical education or disproportionate share payments and are not Medicare-dependent, small rural hospitals. The criteria for identifying these hospitals are set forth in § 412.107.

(j) *Medicare-dependent, small rural hospitals.* For cost reporting periods beginning on or after April 1, 1990, and before October 1, 1994, and for discharges occurring on or after October 1, 1997 and before October 1, 2024, CMS adjusts the prospective payment rates for inpatient operating costs determined under subparts D and E of this part if a hospital is classified as a Medicare-dependent, small rural hospital.

(k) *Essential access community hospitals (EACHs).* If a hospital was designated as an EACH by CMS as described in § 412.109(a) and is located in a rural area as defined in § 412.109(b), CMS determines the prospective payment rate for that hospital, as it does

for sole community hospitals, under § 412.92(d).

[57 FR 39823, Sept. 1, 1992, as amended at 58 FR 30669, May 26, 1993; 62 FR 46028, Aug. 29, 1997; 64 FR 67051, Nov. 30, 1999; 65 FR 47047, Aug. 1, 2000; 70 FR 47485, Aug. 12, 2005; 71 FR 48138, Aug. 18, 2006; 82 FR 38511, Aug. 14, 2017; 83 FR 41701, Aug. 17, 2018; 86 FR 73511, Dec. 27, 2021; 88 FR 59331, Aug. 28, 2023]

### § 412.92 Special treatment: Sole community hospitals.

(a) *Criteria for classification as a sole community hospital.* CMS classifies a hospital as a sole community hospital if it is located more than 35 miles from other like hospitals, or it is located in a rural area (as defined in § 412.64) and meets one of the following conditions:

(1) The hospital is located between 25 and 35 miles from other like hospitals and meets one of the following criteria:

(i) No more than 25 percent of residents who become hospital inpatients or no more than 25 percent of the Medicare beneficiaries who become hospital inpatients in the hospital's service area are admitted to other like hospitals located within a 35-mile radius of the hospital, or, if larger, within its service area;

(ii) The hospital has fewer than 50 beds and the MAC certifies that the hospital would have met the criteria in paragraph (a)(1)(i) of this section were it not for the fact that some beneficiaries or residents were forced to seek care outside the service area due to the unavailability of necessary specialty services at the community hospital; or

(iii) Because of local topography or periods of prolonged severe weather conditions, the other like hospitals are inaccessible for at least 30 days in each 2 out of 3 years.

(2) The hospital is located between 15 and 25 miles from other like hospitals but because of local topography or periods of prolonged severe weather conditions, the other like hospitals are inaccessible for at least 30 days in each 2 out of 3 years.

(3) Because of distance, posted speed limits, and predictable weather conditions, the travel time between the hospital and the nearest like hospital is at least 45 minutes.