

(1) 75 percent of the costs of the new medical service or technology; or

(2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment.

(b)(1) *For discharges occurring before October 1, 2019.* Unless a discharge case qualifies for outlier payment under § 412.84, Medicare will not pay any additional amount beyond the DRG payment plus 50 percent of the estimated costs of the new medical service or technology.

(2) *For discharges occurring on or after October 1, 2019.* Unless a discharge case qualifies for outlier payment under § 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.

(iv) For discharges occurring on or after October 1, 2024, for a medical product that is a gene therapy that is indicated and used specifically for the treatment of sickle cell disease and approved for new technology add-on payments in the FY 2025 IPPS/LTCH PPS final rule, 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; 89 FR 69910, Aug. 28, 2024]

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 de-

scribed 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