

(d) of this section and announce the results in the FEDERAL REGISTER as part of its annual updates and changes to the IPPS. CMS will only consider any particular new medical service or technology for add-on payments under paragraph (b), (c), or (d) of this section.

(2) Except as provided for in paragraph (f)(3) of this section, CMS only considers, for add-on payments for a particular fiscal year, an application for which the new medical service or technology has received FDA marketing authorization by May 1 prior to the particular fiscal year.

(3) A technology for which an application is submitted under an alternative pathway for certain antimicrobial products under paragraph (d) of this section that does not receive FDA marketing authorization by July 1 prior to the particular fiscal year for which the applicant applied for new technology add-on payments may be conditionally approved for the new technology add-on payment for that fiscal year, effective for discharges beginning in the first quarter after FDA marketing authorization is granted, provided that FDA marketing authorization is granted before July 1 of the fiscal year for which the applicant applied for new technology add-on payments.

[66 FR 46924, Sept. 7, 2001, as amended at 68 FR 45469, Aug. 1, 2003; 69 FR 49243, Aug. 11, 2004; 73 FR 48755, Aug. 19, 2008; 74 FR 43997, Aug. 27, 2009; 82 FR 38511, Aug. 14, 2017; 84 FR 42611, Aug. 16, 2019; 85 FR 59020, Sept. 18, 2020; 88 FR 59331, Aug. 28, 2023]

**§ 412.88 Additional payment for new medical service or technology.**

(a) For discharges involving new medical services or technologies that meet the criteria specified in § 412.87, Medicare payment will be:

(1) One of the following:

(i) The full DRG payment (including adjustments for indirect medical education and disproportionate share but excluding outlier payments);

(ii) The payment determined under § 412.4(f) for transfer cases;

(iii) The payment determined under § 412.92(d) for sole community hospitals; or

(iv) The payment determined under § 412.108(c) for Medicare-dependent hospitals; plus

(2)(i) *For discharges occurring before October 1, 2019.* If the costs of the discharge (determined by applying the operating cost-to-charge ratios as described in § 412.84(h)) exceed the full DRG payment, an additional amount equal to the lesser of—

(A) 50 percent of the costs of the new medical service or technology; or

(B) 50 percent of the amount by which the costs of the case exceed the standard DRG payment.

(ii) *For discharges occurring on or after October 1, 2019.* (A) Except as provided under paragraph (a)(2)(ii)(B) of this section, if the costs of the discharge (determined by applying the operating cost-to-charge ratios as described in § 412.84(h)) exceed the full DRG payment, an additional amount equal to the lesser of—

(1) 65 percent of the costs of the new medical service or technology; or

(2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment.

(B) For a medical product designated by FDA as a Qualified Infectious Disease Product or, for discharges occurring on or after October 1, 2020, for a product approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs, if the costs of the discharge (determined by applying the operating cost-to-charge ratios as described in § 412.84(h)) exceed the full DRG payment, an additional amount equal to the lesser of—

(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.

(C) 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, for discharges occurring on or after October 1, 2024, if the costs of the discharge (determined by applying the operating cost-to-charge ratios as described in § 412.84(h)) exceed the full DRG payment, an additional amount equal to the lesser of—

(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