

Medicare beneficiaries who are registered on hospital records as outpatients.

(b) *Scope.* This subpart describes the basis of payment for outpatient hospital services under the prospective payment system. Subpart B sets forth the categories of hospitals and services that are subject to the outpatient hospital prospective payment system and those categories of hospitals and services that are excluded from the outpatient hospital prospective payment system. Subpart C sets forth the basic methodology by which prospective payment rates for hospital outpatient services are determined. Subpart D describes Medicare payment amounts, beneficiary copayment amounts, and methods of payment to hospitals under the hospital outpatient prospective payment system. Subpart E describes how the hospital outpatient prospective payment system may be updated. Subpart F describes limitations on administrative and judicial review. Subpart G describes the transitional payment adjustments that are made before 2004 to limit declines in payment for outpatient services.

§ 419.2 Basis of payment.

(a) *Unit of payment.* Under the hospital outpatient prospective payment system, predetermined amounts are paid for designated services furnished to Medicare beneficiaries. These services are identified by codes established under the Centers for Medicare & Medicaid Services Common Procedure Coding System (HCPCS). The prospective payment rate for each service or procedure for which payment is allowed under the hospital outpatient prospective payment system is determined according to the methodology described in subpart C of this part. The manner in which the Medicare payment amount and the beneficiary copayment amount for each service or procedure are determined is described in subpart D of this part.

(b) *Determination of hospital outpatient prospective payment rates: Packaged costs.* The prospective payment system establishes a national payment rate, standardized for geographic wage differences, that includes operating and capital-related costs that are integral,

ancillary, supportive, dependent, or adjunctive to performing a procedure or furnishing a service on an outpatient basis. In general, these packaged costs may include, but are not limited to, the following items and services, the payment for which are packaged or conditionally packaged into the payment for the related procedures or services.

- (1) Use of an operating suite, procedure room, or treatment room;
- (2) Use of recovery room;
- (3) Observation services;
- (4) Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations;
- (5) Supplies and equipment for administering and monitoring anesthesia or sedation;
- (6) Intraocular lenses (IOLs);
- (7) Ancillary services;
- (8) Capital-related costs;
- (9) Implantable items used in connection with diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests;
- (10) Durable medical equipment that is implantable;
- (11) Implantable and insertable medical items and devices, including, but not limited to, prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of these devices;
- (12) Costs incurred to procure donor tissue other than corneal tissue.
- (13) Image guidance, processing, supervision, and interpretation services;
- (14) Intraoperative items and services;
- (15) Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including but not limited to, diagnostic radiopharmaceuticals, contrast agents, and pharmacologic stress agents);
- (16) Drugs and biologicals that function as supplies when used in a surgical procedure (including, but not limited to, skin substitutes and similar products that aid wound healing and implantable biologicals);

Centers for Medicare & Medicaid Services, HHS

§419.21

(17) Certain clinical diagnostic laboratory tests; and

(18) Certain services described by add-on codes.

(c) *Determination of hospital outpatient prospective payment rates: Excluded costs.* The following costs are excluded from the hospital outpatient prospective payment system.

(1) The costs of direct graduate medical education activities as described in §§413.75 through 413.83 of this chapter.

(2) The costs of nursing and allied health programs as described in §413.85 of this chapter.

(3) The costs associated with interns and residents not in approved teaching programs as described in §415.202 of this chapter.

(4) The costs of teaching physicians attributable to Part B services for hospitals that elect cost-based reimbursement for teaching physicians under §415.160.

(5) The reasonable costs of anesthesia services furnished to hospital outpatients by qualified nonphysician anesthesiologists (certified registered nurse anesthetists and anesthesiologists' assistants) employed by the hospital or obtained under arrangements, for hospitals that meet the requirements under §412.113(c) of this chapter.

(6) Bad debts for uncollectible deductibles and coinsurances as described in §413.89(b) of this chapter.

(7) Organ acquisition costs paid under Part B.

(8) Corneal tissue acquisition or procurement costs for corneal transplant procedures.

[65 FR 18542, Apr. 7, 2000, as amended at 66 FR 59922, Nov. 30, 2001; 70 FR 47490, Aug. 12, 2005; 77 FR 68558, Nov. 15, 2012; 78 FR 75196, Dec. 10, 2013; 79 FR 67031, Nov. 10, 2014; 80 FR 70606, Nov. 13, 2015]

Subpart B—Categories of Hospitals and Services Subject to and Excluded From the Hospital Outpatient Prospective Payment System

§419.20 Hospitals subject to the hospital outpatient prospective payment system.

(a) *Applicability.* The hospital outpatient prospective payment system is applicable to any hospital partici-

pating in the Medicare program, except those specified in paragraph (b) of this section, for services furnished on or after August 1, 2000.

(b) *Hospitals excluded from the outpatient prospective payment system.* (1) Those services furnished by Maryland hospitals that are paid under a cost containment waiver in accordance with section 1814(b)(3) of the Act are excluded from the hospital outpatient prospective payment system.

(2) Critical access hospitals (CAHs) are excluded from the hospital outpatient prospective payment system.

(3) A hospital located outside one of the 50 States, the District of Columbia, and Puerto Rico is excluded from the hospital outpatient prospective payment system.

(4) A hospital of the Indian Health Service.

(5) A rural emergency hospital (REH).

[65 FR 18542, Apr. 7, 2000, as amended at 66 FR 59922, Nov. 30, 2001; 88 FR 82180, Nov. 22, 2023]

§419.21 Hospital services subject to the outpatient prospective payment system.

Except for services described in §419.22, effective for services furnished on or after July 1, 2000, payment is made under the hospital outpatient prospective payment system for the following:

(a) Medicare Part B services furnished to hospital outpatients designated by the Secretary under this part.

(b) Services designated by the Secretary that are covered under Medicare Part B when furnished to hospital inpatients who are either not entitled to benefits under Part A or who have exhausted their Part A benefits but are entitled to benefits under Part B of the program.

(c) Partial hospitalization services and intensive outpatient services furnished by community mental health centers (CMHCs).

(d) The following medical and other health services furnished by a home health agency (HHA) to patients who

§ 419.22

42 CFR Ch. IV (10–1–24 Edition)

are not under an HHA plan or treatment or by a hospice program furnishing services to patients outside the hospice benefit:

- (1) Antigens.
- (2) Splints and casts.
- (3) Hepatitis B vaccine.

(e)(1) Effective January 1, 2005 through December 31, 2008, an initial preventive physical examination, as defined in § 410.16 of this chapter, if the examination is performed no later than 6 months after the individual's initial Part B coverage date that begins on or after January 1, 2005.

(2) Effective January 1, 2009, an initial preventive physical examination, as defined in § 410.16 of this chapter, if the examination is performed no later than 12 months after the date of the individual's initial enrollment in Part B.

[65 FR 18542, Apr. 7, 2000, as amended at 67 FR 66813, Nov. 1, 2002; 69 FR 65863, Nov. 15, 2004; 71 FR 68227, Nov. 24, 2006; 75 FR 72265, Nov. 24, 2010; 88 FR 82180, Nov. 22, 2023]

§ 419.22 Hospital services excluded from payment under the hospital outpatient prospective payment system.

The following services are not paid for under the hospital outpatient prospective payment system (except when packaged as a part of a bundled payment):

(a) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(b) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(c) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(d) Certified nurse-midwife services, as defined in section 1861(gg) of the Act.

(e) Services of qualified psychologists, as defined in section 1861(ii) of the Act.

(f) Services of an anesthetist as defined in § 410.69 of this chapter.

(g) Clinical social worker services as defined in section 1861(hh)(2) of the Act.

(h) Physical therapy services, speech-language pathology services, and occupational therapy services described in section 1833(a)(8) of the Act for which

payment is made under the fee schedule described in section 1834(k) of the Act.

(i) Ambulance services, as described in section 1861(v)(1)(U) of the Act, or, if applicable, the fee schedule established under section 1834(l).

(j) Except as provided in § 419.2(b)(11), prosthetic devices and orthotic devices.

(k) Except as provided in § 419.2(b)(10), durable medical equipment supplied by the hospital for the patient to take home.

(l) Except as provided in § 419.2(b)(17), clinical diagnostic laboratory tests.

(m)(1) Services provided on or before December 31, 2010, for patients with ESRD that are paid under the ESRD composite rate and drugs and supplies furnished during dialysis but not included in the composite rate.

(2) Renal dialysis services provided on or after January 1, 2011, for patients with ESRD that are paid under the ESRD benefit, as described in subpart H of part 413 of this chapter.

(n) Services and procedures that the Secretary designates as requiring inpatient care.

(o) Hospital outpatient services furnished to SNF residents (as defined in § 411.15(p) of this chapter) as part of the patient's resident assessment or comprehensive care plan (and thus included under the SNF PPS) that are furnished by the hospital "under arrangements" but billable only by the SNF, regardless of whether or not the patient is in a Part A SNF stay.

(p) Services that are not covered by Medicare by statute.

(q) Services that are not reasonable or necessary for the diagnosis or treatment of an illness or disease.

(r) Services defined in § 419.21(b) that are furnished to inpatients of hospitals that do not submit claims for outpatient services under Medicare Part B.

(s) Effective December 8, 2003, screening mammography services and effective January 1, 2005, diagnostic mammography services.

(t) Effective January 1, 2011, annual wellness visit providing personalized prevention plan services as defined in § 410.15 of this chapter.

(u) Outpatient diabetes self-management training.