

to, skin substitutes and similar products that aid wound healing and implantable biologicals);

(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 participating 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.

[65 FR 18542, Apr. 7, 2000, as amended at 66 FR 59922, Nov. 30, 2001]

### **§ 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.

## § 419.22

## 42 CFR Ch. IV (10–1–23 Edition)

(c) Partial hospitalization 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 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]

### **§ 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.

## Centers for Medicare & Medicaid Services, HHS

## § 419.31

(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.

(v) Effective January 1, 2017, items and services that do not meet the definition of excepted items and services under § 419.48(a).

[65 FR 18542, Apr. 7, 2000, as amended at 66 FR 59922, Nov. 30, 2001; 69 FR 65863, Nov. 15, 2004; 75 FR 72265, Nov. 24, 2010; 78 FR 50969, Aug. 19, 2013; 78 FR 75196, Dec. 10, 2013; 79 FR 67031, Nov. 10, 2014; 81 FR 79879, Nov. 14, 2016; 82 FR 35, Jan. 3, 2017; 85 FR 86302, Dec. 29, 2020; 86 FR 63993, Nov. 16, 2021]

### **§ 419.23 Removal of services and procedures from the Inpatient Only List.**

(a) *Inpatient Only List.* CMS maintains a list of services and procedures that the Secretary designates as requiring inpatient care under § 419.22(n) that are not paid under the hospital outpatient prospective payment system. This list is referred to as the Inpatient Only List.

(b) *Removals from the Inpatient Only List.* CMS assesses annually whether a service or procedure on the Inpatient Only List described in paragraph (a) of this section should be removed from the list by determining whether the service or procedure meets at least one of the following criteria:

(1) Most outpatient departments are equipped to provide the service or procedure to the Medicare population.

(2) The simplest service or procedure described by the code may be performed in most outpatient departments.

(3) The service or procedure is related to codes that CMS has already removed from the Inpatient Only List described in paragraph (a) of this section.

(4) CMS determines that the service or procedure is being performed in numerous hospitals on an outpatient basis.

(5) CMS determines that the service or procedure can be appropriately and safely performed in an ambulatory surgical center, and is specified as a cov-

ered ambulatory surgical procedure under § 416.166 of this chapter, or CMS has proposed to specify it as a covered ambulatory surgical procedure under § 416.166 of this chapter.

[86 FR 63993, Nov. 16, 2021]

### **Subpart C—Basic Methodology for Determining Prospective Payment Rates for Hospital Outpatient Services**

#### **§ 419.30 Base expenditure target for calendar year 1999.**

(a) CMS estimates the aggregate amount that would be payable for hospital outpatient services in calendar year 1999 by summing—

(1) The total amounts that would be payable from the Trust Fund for covered hospital outpatient services without regard to the outpatient prospective payment system described in this part; and

(2) The total amounts of coinsurance that would be payable by beneficiaries to hospitals for covered hospital outpatient services without regard to the outpatient prospective payment system described in this part.

(b) The estimated aggregate amount under paragraph (a) of this section is determined as though the deductible required under section 1833(b) of the Act did not apply.

#### **§ 419.31 Ambulatory payment classification (APC) system and payment weights.**

(a) *APC groups.* (1) CMS classifies outpatient services and procedures that are comparable clinically and in terms of resource use into APC groups. Except as specified in paragraph (a)(2) of this section, items and services within a group are not comparable with respect to the use of resources if the highest geometric mean cost for an item or service within the group is more than 2 times greater than the lowest geometric mean cost for an item or service within the group.

(2) CMS may make exceptions to the requirements set forth in paragraph (a)(1) in unusual cases, such as low volume items and services, but may not make such an exception in the case of