

(ii) Their customary charges for each surgical procedure furnished for the period.

[47 FR 34094, Aug. 5, 1982, as amended at 56 FR 8845, Mar. 1, 1991]

Subpart F—Coverage, Scope of ASC Services, and Prospective Payment System for ASC Services Furnished on or After January 1, 2008

SOURCE: 72 FR 42545, Aug. 2, 2007, unless otherwise noted.

§ 416.160 Basis and scope.

(a) *Statutory basis.* (1) Section 1833(i)(2)(D) of the Act requires the Secretary to implement a revised payment system for payment of surgical services furnished in ASCs. The statute requires that, in the year such system is implemented, the system shall be designed to result in the same amount of aggregate expenditures for such services as would be made if there was no requirement for a revised payment system. The revised payment system shall be implemented no earlier than January 1, 2006, and no later than January 1, 2008. There shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the classification system, the relative weights, payment amounts, and the geographic adjustment factor, if any, of the revised payment system.

(2) Section 1833(a)(1)(G) of the Act provides that, beginning with the implementation date of a revised payment system for ASC facility services furnished in connection with a surgical procedure pursuant to section 1833(i)(1)(A) of the Act, the amount paid shall be 80 percent of the lesser of the actual charge for such services or the amount determined by the Secretary under the revised payment system.

(3) Section 1833(i)(1)(A) of the Act requires the Secretary to specify the surgical procedures that can be performed safely on an ambulatory basis in an ASC.

(4) Section 1834(d) of the Act specifies that, when screening colonoscopies or screening flexible sigmoidoscopies are

performed in an ASC or hospital outpatient department, payment shall be based on the lesser of the amount under the fee schedule that would apply to such services if they were performed in a hospital outpatient department in an area or the amount under the fee schedule that would apply to such services if they were performed in an ambulatory surgical center in the same area. Section 1834(d) of the Act further specifies that the coinsurance for screening flexible sigmoidoscopy and screening colonoscopy procedures is 25 percent of the payment amount. Section 1834(d) of the Act also specifies that, in the case of screening flexible sigmoidoscopy and screening colonoscopy services, their payment amounts must not exceed the payment rates established for the related diagnostic services. Section 1833(b)(8) of the Act specifies that the Part B deductible shall not apply with respect to colorectal screening tests as described in section 1861(pp)(1) of the Act, which include screening colonoscopies and screening flexible sigmoidoscopies.

(b) *Scope.* This subpart sets forth—

(1) The scope of ASC services and the criteria for determining the covered surgical procedures for which Medicare provides payment for the associated facility services and covered ancillary services;

(2) The basis of payment for facility services and for covered ancillary services furnished in an ASC in connection with a covered surgical procedure;

(3) The methodologies by which Medicare determines payment amounts for ASC services.

§ 416.161 Applicability of this subpart.

The provisions of this subpart apply to ASC services furnished on or after January 1, 2008.

§ 416.163 General rules.

(a) Payment is made under this subpart for ASC services specified in §§ 416.164(a) and (b) furnished to Medicare beneficiaries by a participating ASC in connection with covered surgical procedures as determined by the Secretary in accordance with § 416.166.

(b) Payment for physicians' services and payment for anesthesiologists' services

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are made in accordance with Part 414 of this subchapter.

(c) Payment for items and services other than physicians' and anesthesiologists' services, as specified in §416.164(c), is made in accordance with §410.152 of this subchapter.

§416.164 Scope of ASC services.

(a) *Included facility services.* ASC services for which payment is packaged into the ASC payment for a covered surgical procedure under §416.166 include, but are not limited to—

(1) Nursing, technician, and related services;

(2) Use of the facility where the surgical procedures are performed;

(3) Any laboratory testing performed under a Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate of waiver;

(4) Drugs and biologicals for which separate payment is not allowed under the hospital outpatient prospective payment system (OPPS);

(5) Medical and surgical supplies not on pass-through status under Subpart G of Part 419 of this subchapter;

(6) Equipment;

(7) Surgical dressings;

(8) Implanted prosthetic devices, including intraocular lenses (IOLs), and related accessories and supplies not on pass-through status under subpart G of part 419 of this subchapter;

(9) Implanted DME and related accessories and supplies not on pass-through status under subpart G of part 419 of this subchapter;

(10) Splints and casts and related devices;

(11) Radiology services for which separate payment is not allowed under the OPPS, and other diagnostic tests or interpretive services that are integral to a surgical procedure;

(12) Administrative, recordkeeping and housekeeping items and services;

(13) Materials, including supplies and equipment for the administration and monitoring of anesthesia; and

(14) Supervision of the services of an anesthesiologist by the operating surgeon.

(b) *Covered ancillary services.* Ancillary items and services that are integral to a covered surgical procedure, as defined in §416.166, and for which separate payment is allowed include:

(1) Brachytherapy sources;

(2) Certain implantable items that have pass-through status under the OPPS;

(3) Certain items and services that CMS designates as contractor-priced, including, but not limited to, the procurement of corneal tissue;

(4) Certain drugs and biologicals for which separate payment is allowed under the OPPS;

(5) Certain radiology services for which separate payment is allowed under the OPPS.

(c) *Excluded services.* ASC services do not include items and services outside the scope of ASC services for which payment may be made under part 414 of this subchapter in accordance with §410.152, including, but not limited to—

(1) Physicians' services (including surgical procedures and all preoperative and postoperative services that are performed by a physician);

(2) Anesthesiologists' services;

(3) Radiology services (other than those integral to performance of a covered surgical procedure);

(4) Diagnostic procedures (other than those directly related to performance of a covered surgical procedure);

(5) Ambulance services;

(6) Leg, arm, back, and neck braces other than those that serve the function of a cast or splint;

(7) Artificial limbs;

(8) Nonimplantable prosthetic devices and DME.

§416.166 Covered surgical procedures.

(a) *Covered surgical procedures.* Effective for services furnished on or after January 1, 2008, covered surgical procedures are those procedures that meet the general standards described in paragraph (b) of this section (whether commonly furnished in an ASC or a physician's office) and are not excluded under paragraph (c) of this section.

(b) *General standards.* Subject to the exclusions in paragraph (c) of this section, covered surgical procedures are surgical procedures specified by the Secretary and published in the FEDERAL REGISTER that are separately paid under the OPPS, that would not be expected to pose a significant safety risk