

conducts a survey of a randomly selected sample of participating ASCs to collect data for analysis or reevaluation of payment rates.

(2) CMS notifies the selected ASCs by mail of their selection and of the form and content of the report the ASCs are required to submit within 60 days of the notice.

(3) If the facility does not submit an adequate report in response to CMS's survey request, CMS may terminate the agreement to participate in the Medicare program as an ASC.

(4) CMS may grant a 30-day postponement of the due date for the survey report if it determines that the facility has demonstrated good cause for the delay.

(b) *Requirements for ASCs.* ASCs must—

(1) Maintain adequate financial records, in the form and containing the data required by CMS, to allow determination of the payment rates for covered surgical procedures furnished to Medicare beneficiaries under this subpart.

(2) Within 60 days of a request from CMS submit, in the form and detail as may be required by CMS, a report of—

(i) Their operations, including the allowable costs actually incurred for the period and the actual number and kinds of surgical procedures furnished during the period; and

(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. The statute provides that the Secretary may implement a reduction in any annual update for failure to report on quality measures as specified by the Secretary. The statute also requires that, for CY 2011 and each subsequent year, any annual update to the ASC payment system, after application of any reduction in the annual update for failure to report on quality measures as specified by the Secretary, be reduced by a productivity adjustment. 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 also specifies that, in the case of

screening flexible sigmoidoscopy and screening colonoscopy services, the payment amounts must not exceed the payment rates established for the related diagnostic services.

(5) Section 1833(a)(1) of the Act requires 100 percent payment for preventive services described in section 1861(ww)(2) of the Act (excluding electrocardiograms) to which the United States Preventive Services Task Force (USPSTF) has given a grade of A or B for any indication or population. Section 1833(b)(1) of the Act also specifies that the Part B deductible shall not apply with respect to preventive services described in section 1861(ww)(2) of the Act (excluding electrocardiograms) to which the USPSTF has given a grade of A or B for any indication or population.

(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.

[72 FR 42545, Aug. 2, 2007, as amended at 75 FR 72264, Nov. 24, 2010; 77 FR 68558, Nov. 15, 2012]

§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 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), with the exception of non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS under §416.174;

(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, except certain diagnostic tests for which separate payment is allowed under the OPPS;

(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

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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 acquisition or procurement of corneal tissue for corneal transplant procedures;
- (4) Certain drugs and biologicals for which separate payment is allowed under the OPPS;
- (5) Certain radiology services and certain diagnostic tests for which separate payment is allowed under the OPPS; and
- (6) Non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS under § 416.174.

(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 pre-operative and postoperative services that are performed by a physician);
- (2) Anesthetists' 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.

[72 FR 42545, Aug. 2, 2007, as amended at 79 FR 67030, Nov. 10, 2014; 80 FR 70604, Nov. 13, 2015; 83 FR 59178, Nov. 21, 2018; 86 FR 63992, Nov. 16, 2021]

§ 416.166 Covered surgical procedures.

(a) *Covered surgical procedures.* Effective for services furnished on or after January 1, 2022, 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 and/or via the internet on the CMS website that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure.

(c) *General exclusions.* Notwithstanding paragraph (b) of this section, covered surgical procedures do not include those surgical procedures that —

- (1) Generally result in extensive blood loss;
- (2) Require major or prolonged invasion of body cavities;
- (3) Directly involve major blood vessels;
- (4) Are generally emergent or life-threatening in nature;
- (5) Commonly require systemic thrombolytic therapy;
- (6) Are designated as requiring inpatient care under § 419.22(n) of this chapter;
- (7) Can only be reported using a CPT unlisted surgical procedure code; or
- (8) Are otherwise excluded under § 411.15 of this chapter.

(d) *Additions to the list of ASC covered surgical procedures.* Surgical procedures are added to the list of ASC covered surgical procedures as follows:

(1) *Pre-proposed rule covered procedures list (CPL) recommendation process.* On or after January 1, 2024, an external party may recommend a surgical procedure by March 1 of a calendar year for the list of ASC covered surgical procedures for the following calendar year.

(2) *Inclusion in rulemaking.* If CMS identifies a surgical procedure that meets the requirements at paragraph (a) of this section, including a surgical procedure nominated under paragraph (d)(1) of this section, it will propose to add the surgical procedure to the list of

ASC covered surgical procedures in the next available annual rulemaking.

[86 FR 63992, Nov. 16, 2021, as amended at 87 FR 72291, Nov. 23, 2022]

§ 416.167 Basis of payment.

(a) *Unit of payment.* Under the ASC payment system, prospectively determined amounts are paid for ASC services furnished to Medicare beneficiaries in connection with covered surgical procedures. Covered surgical procedures and covered ancillary services are identified by codes established under the Healthcare Common Procedure Coding System (HCPCS). The unadjusted national payment rate is determined according to the methodology described in §416.171. The manner in which the Medicare payment amount and the beneficiary coinsurance amount for each ASC service is determined is described in §416.172.

(b) *Ambulatory payment classification (APC) groups and payment weights.* (1) ASC covered surgical procedures are classified using the APC groups described in §419.31 of this subchapter.

(2) For purposes of calculating ASC national payment rates under the methodology described in §416.171, except as specified in paragraph (b)(3) of this section, an ASC relative payment weight is determined based on the APC relative payment weight for each covered surgical procedure and covered ancillary service that has an applicable APC relative payment weight described in §419.31 of this subchapter.

(3) Notwithstanding paragraph (b)(2) of this section, the relative payment weights for services paid in accordance with §416.171(d) are determined so that the national ASC payment rate does not exceed the unadjusted nonfacility practice expense amount paid under the Medicare physician fee schedule for such procedures under subpart B of part 414 of this subchapter.

§ 416.171 Determination of payment rates for ASC services.

(a) *Standard methodology.* The standard methodology for determining the national unadjusted payment rate for ASC services is to calculate the product of the applicable conversion factor and the relative payment weight estab-

lished under §416.167(b), unless otherwise indicated in this section.

(1) *Conversion factor for CY 2008.* CMS calculates a conversion factor so that payment for ASC services furnished in CY 2008 would result in the same aggregate amount of expenditures as would be made if the provisions in this Subpart F did not apply, as estimated by CMS.

(2) *Conversion factor for CY 2009 and subsequent calendar years.* The conversion factor for a calendar year is equal to the conversion factor calculated for the previous year, updated as follows:

(i) For CY 2009, the update is equal to zero percent.

(ii) For CY 2010 through CY 2018, the update is the Consumer Price Index for All Urban Consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.

(iii) For CY 2019 through CY 2023, the update is the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act.

(iv) For CY 2024 and subsequent years, the update is the Consumer Price Index for All Urban Consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.

(v) For CY 2014 through CY 2018, the Consumer Price Index for All Urban Consumers update determined under paragraph (a)(2)(ii) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(vi) For CY 2019 through CY 2023, the hospital inpatient market basket update determined under paragraph (a)(2)(iii) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(vii) For CY 2024 and subsequent years, the Consumer Price Index for All Urban Consumers update determined under paragraph (a)(2)(iv) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the

standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(viii)(A) For CY 2011 through CY 2018, the Consumer Price Index for All Urban Consumers determined under paragraph (a)(2)(ii) of this section, after application of any reduction under paragraph (a)(2)(iv) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(B) For CY 2019 through CY 2023, the hospital inpatient market basket update determined under paragraph (a)(2)(iii) of this section, after application of any reduction under paragraph (a)(2)(vi) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(C) For CY 2024 and subsequent years, the Consumer Price Index for All Urban Consumers determined under paragraph (a)(2)(iv) of this section, after application of any reduction under paragraph (a)(2)(vii) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(D) The application of the provisions of paragraph (a)(2)(viii)(A), (B), or (C) of this section may result in the update being less than zero percent for a year, and may result in payment rates for a year being less than the payment rates for the preceding year.

(b) *Exception.* The national ASC payment rates for the following items and services are not determined in accordance with paragraph (a) of this section but are paid an amount derived from the payment rate for the equivalent item or service set under the payment system established in part 419 of this subchapter as updated annually in the FEDERAL REGISTER and/or via the Internet on the CMS Web site. If a payment rate is not available, the following items and services are designated as contractor-priced:

(1) Covered ancillary services specified in § 416.164(b), with the exception of radiology services and certain diagnostic tests as provided in § 416.164(b)(5) and non-opioid pain management drugs and biologicals that function as a sup-

ply when used in a surgical procedure as determined by CMS under § 416.174.

(2) The device portion of device-intensive procedures, which are procedures that—

(i) Involve implantable devices assigned a CPT or HCPCS code;

(ii) Utilize devices (including single-use devices) that must be surgically inserted or implanted; and

(iii) Have a HCPCS code-level device offset of greater than 30 percent when calculated according to the standard OPPS ASC ratesetting methodology.

(3) Procedures using certain separately paid implantable devices that are approved for transitional pass-through payment in accordance with § 419.66 of this subchapter.

(4) Notwithstanding paragraph (b)(2) of this section, procedures assigned to Low Volume APCs where the otherwise applicable payment rate calculated based on the standard methodology for such procedures described in paragraph (b) of this section would exceed the payment rate for the equivalent service set under the payment system established under part 419 of this chapter, for which the payment rate will be set at an amount equal to the amount under that payment system.

(c) *Transitional payment rates.* (1) ASC payment rates for CY 2008 are a transitional blend of 75 percent of the CY 2007 ASC payment rate for a covered surgical procedure on the CY 2007 ASC list of surgical procedures and 25 percent of the payment rate for the procedure calculated under the methodology described in paragraph (a) of this section.

(2) ASC payment rates for CY 2009 are a transitional blend of 50 percent of the CY 2007 ASC payment rate for a covered surgical procedure on the CY 2007 ASC list of surgical procedures and 50 percent of the payment rate for the procedure calculated under the methodology described in paragraph (a) of this section.

(3) ASC payment rates for CY 2010 are a transitional blend of 25 percent of the CY 2007 ASC payment rate for a covered surgical procedure on the CY 2007 ASC list of surgical procedures and 75 percent of the payment rate for the procedure calculated under the methodology described in paragraph (a) of this section.

(4) The national ASC payment rate for CY 2011 and subsequent calendar years for a covered surgical procedure designated in accordance with §416.166 is the payment rates for the procedure calculated under the methodology described in paragraph (a) of this section.

(5) Covered ancillary services described in §416.164(b) and surgical procedures identified as covered when performed in an ASC under §416.166 for the first time beginning on or after January 1, 2008, are not subject to the transitional payment rates applicable in CYs 2008 through 2010 for ASC facility services.

(d) *Limitation on payment rates for office-based surgical procedures and covered ancillary radiology services and certain diagnostic tests.* Notwithstanding the provisions of paragraph (a) of this section, for any covered surgical procedure under §416.166 that CMS determines is commonly performed in physicians' offices or for any covered ancillary radiology service or diagnostic test under §416.164(b)(5), excluding those listed in paragraphs (d)(1) and (d)(2) of this section, the national unadjusted ASC payment rates for these procedures and services will be the lesser of the amount determined under paragraph (a) of this section or the amount calculated at the non-facility practice expense relative value units under §414.22(b)(5)(i)(B) of this chapter multiplied by the conversion factor described in §414.20(a)(3) of this chapter.

(1) The national unadjusted ASC payment rate for covered ancillary radiology services that involve certain nuclear medicine procedures will be the amount determined under paragraph (a) of this section.

(2) The national unadjusted ASC payment rate for covered ancillary radiology services that use contrast agents will be the amount determined under paragraph (a) of this section.

(e) *Budget neutrality.* (1) For CY 2008, CMS establishes the conversion factor to result in budget neutrality as estimated by CMS in accordance with paragraph (a)(1) of this section.

(2) For CY 2009 and subsequent calendar years, CMS adjusts the ASC relative payment weights under §416.167(b)(2) as needed so that any up-

dates and adjustments made under §419.50(a) of this subchapter are budget neutral as estimated by CMS.

[72 FR 42545, Aug. 2, 2007, as amended at 75 FR 72264, Nov. 24, 2010; 76 FR 74582, Nov. 30, 2011; 77 FR 277, Jan. 4, 2012; 77 FR 68558, Nov. 15, 2012; 79 FR 67030, Nov. 10, 2014; 81 FR 79879, Nov. 14, 2016; 83 FR 59178, Nov. 21, 2018; 84 FR 61490, Nov. 12, 2019; 86 FR 63993, Nov. 16, 2021]

§416.172 Adjustments to national payment rates.

(a) *General rule.* Contractors adjust the payment rates established for ASC services to determine Medicare program payment and beneficiary coinsurance amounts in accordance with paragraphs (b) through (g) of this section.

(b) *Lesser of actual charge or geographically adjusted payment rate.* Payments to ASCs equal 80 percent of the lesser of—

(1) The actual charge for the service; or

(2) The geographically adjusted payment rate determined under this subpart.

(c) *Geographic adjustment—(1) General rule.* Except as provided in paragraph (c)(2) of this section, the national ASC payment rates established under §416.171 for covered surgical procedures are adjusted for variations in ASC labor costs across geographic areas using wage index values, labor and nonlabor percentages, and localities specified by the Secretary.

(2) *Exception.* The geographic adjustment is not applied to the payment rates set for drugs, biologicals, devices with OPPS transitional pass-through payment status, and brachytherapy sources.

(d) *Deductibles and coinsurance.* Part B deductible and coinsurance amounts apply as specified in §§410.152(a) and (i)(2) of this subchapter.

(e) *Payment reductions for multiple surgical procedures—(1) General rule.* Except as provided in paragraph (e)(2) of this section, when more than one covered surgical procedure for which payment is made under the ASC payment system is performed during an operative session, the Medicare program payment amount and the beneficiary coinsurance amount are based on—

(i) 100 percent of the applicable ASC payment amount for the procedure

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with the highest national unadjusted ASC payment rate; and

(ii) 50 percent of the applicable ASC payment amount for all other covered surgical procedures.

(2) *Exception: Procedures not subject to multiple procedure discounting.* CMS may apply any policies or procedures used with respect to multiple procedures under the prospective payment system for hospital outpatient department services under Part 419 of this subchapter as may be consistent with the equitable and efficient administration of this part.

(f) *Interrupted procedures.* (1) Subject to the provisions of paragraph (f)(2) of this section, when a covered surgical procedure or covered ancillary service is terminated prior to completion due to extenuating circumstances or circumstances that threaten the well-being of the patient, the Medicare program payment amount and the beneficiary coinsurance amount are based on one of the following:

(i) The full program and beneficiary coinsurance amounts if the procedure for which anesthesia is planned is discontinued after the induction of anesthesia or after the procedure is started;

(ii) One-half of the full program and beneficiary coinsurance amounts if the procedure for which anesthesia is planned is discontinued after the patient is prepared for surgery and taken to the room where the procedure is to be performed but before the anesthesia is induced; or

(iii) One-half of the full program and beneficiary coinsurance amounts if a covered surgical procedure or covered ancillary service for which anesthesia is not planned is discontinued after the patient is prepared and taken to the room where the service is to be provided.

(2) Beginning CY 2016, if the covered surgical procedure is a device-intensive procedure, the full device portion of the ASC device-intensive procedure is removed prior to determining the Medicare program payment amount and the beneficiary coinsurance amount identified in paragraph (f)(1)(ii) of this section.

(g) *Payment adjustment for new technology intraocular lenses (NTIOLs).* A payment adjustment will be made for

insertion of an IOL approved as belonging to a class of NTIOLs as defined in subpart G.

(h) *Special payment for certain code combinations—*(1) *Eligibility.* A code combination is eligible for the payment specified in paragraph (h)(2) of this section if the code combination is—

(i) Eligible for a comprehensive APC (C-APC) complexity adjustment under the OPPS; and

(ii) Comprised of a separately payable surgical procedure, that is listed on the ASC Covered Procedures list (§ 416.166), and one or more packaged add-on codes that are listed on the ASC covered procedures or ancillary services lists (§ 416.164(b)).

(2) *Calculation of payment.* (i) Except as specified in paragraph (h)(2)(ii) of this section, CMS calculates the payment for code combinations that meet the eligibility requirements in paragraph (h)(1) of this section by applying the methodology specified in § 416.171(a) to the OPPS C-APC complexity-adjusted relative weights.

(ii) For primary procedures assigned device-intensive status that are a component of a code combination that is eligible for payment under paragraph (h)(2) of this section, the primary procedure of the code combination retains its device-intensive status, and—

(A) The device portion is equivalent to the device portion of the device-intensive APC under the OPPS (§ 419.44(b) of this subchapter); and

(B) The non-device portion is calculated in accordance with the methodology specified in § 416.171(a).

[72 FR 42545, Aug. 2, 2007, as amended at 80 FR 70604, Nov. 13, 2015; 87 FR 72291, Nov. 23, 2022]

§ 416.173 Publication of revised payment methodologies and payment rates.

CMS publishes annually, through notice and comment rulemaking in the FEDERAL REGISTER and/or via the Internet on the CMS Web site, the payment methodologies and payment rates for ASC services and designates the covered surgical procedures and covered ancillary services for which CMS will

make an ASC payment and other revisions as appropriate.

[76 FR 74582, Nov. 30, 2011]

§ 416.174 Payment for non-opioid pain management drugs and biologicals that function as supplies in surgical procedures.

(a) *Eligibility for separate payment for non-opioid pain management drugs and biologicals.* Beginning on or after January 1, 2022, a non-opioid pain management drug or biological that functions as a surgical supply is eligible for separate payment for an applicable calendar year if CMS determines it meets the following requirements through that year's rulemaking:

(1) The drug is approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), under an abbreviated new drug application under section 505(j), or, in the case of a biological product, is licensed under section 351 of the Public Health Service Act. The product has an FDA approved indication for pain management or analgesia.

(2) The per-day cost of the drug or biological estimated by CMS for the year exceeds the OPPS drug packaging threshold set for such year through notice and comment rulemaking.

(3) The drug or biological does not have transitional pass-through payment status under § 419.64 of this subchapter. In the case where a drug or biological otherwise meets the requirements under this section and has transitional pass-through payment status that expires during the calendar year, the drug or biological will qualify for separate payment as specified in this paragraph (a) during such calendar year on the first day of the next calendar year quarter following the expiration of its pass-through status.

(4) The drug or biological is not already separately payable in the OPPS or ASC payment system under a policy other than the one specified in this section.

(b) [Reserved]

[86 FR 63993, Nov. 16, 2021, as amended at 87 FR 72291, Nov. 23, 2022]

§ 416.178 Limitations on administrative and judicial review.

There is no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following:

- (a) The classification system;
- (b) Relative weights;
- (c) Payment amounts; and
- (d) Geographic adjustment factors.

§ 416.179 Payment and coinsurance reduction for devices replaced without cost or when full or partial credit is received.

(a) *General rule.* CMS reduces the amount of payment for a covered surgical procedure for which CMS determines that a significant portion of the payment is attributable to the cost of an implanted device not on pass-through status under subpart G of part 419 of this subchapter when one of the following situations occur:

(1) The device is replaced without cost to the ASC or the beneficiary;

(2) The ASC receives full credit for the cost of a replaced device; or

(3) The ASC receives partial credit for the cost of a replaced device but only where the amount of the device credit is greater than or equal to 50 percent of the cost of the new replacement device being implanted.

(b) *Amount of reduction to the ASC payment for the covered surgical procedure.* (1) The amount of the reduction to the ASC payment made under paragraphs (a)(1) and (a)(2) of this section is calculated in the same manner as the device payment reduction that would be applied to the ASC payment for the covered surgical procedure in order to remove predecessor device costs so that the ASC payment amount for a device with pass-through status under § 419.66 of this subchapter represents the full cost of the device, and no packaged device payment is provided through the ASC payment for the covered surgical procedure.

(2) The amount of the reduction to the ASC payment made under paragraph (a)(3) of this section is 50 percent of the payment reduction that would be calculated under paragraph (b)(1) of this section.

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(c) *Amount of beneficiary coinsurance.* The beneficiary coinsurance is calculated based on the ASC payment for the covered surgical procedure after application of the reduction under paragraph (b) of this section.

[72 FR 42545, Aug. 2, 2007, as amended at 72 FR 66932, No. 27, 2007]

Subpart G—Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Service Centers

SOURCE: 71 FR 68226, Nov. 24, 2006, unless otherwise noted.

§ 416.180 Basis and scope.

(a) *Basis.* This subpart implements section 141 of Public Law 103-432, which provides for adjustments to payment amounts for new technology intraocular lenses (IOLs) furnished at ambulatory surgical centers (ASCs).

(b) *Scope.* This subpart sets forth—

(1) The process for interested parties to request that CMS review the appropriateness of the ASC facility fee for insertion of an IOL. This process includes a review of whether that payment is reasonable and related to the cost of acquiring a lens determined by CMS as belonging to a class of new technology IOLs;

(2) Factors that CMS considers for determination of a new class of new technology IOLs; and

(3) Application of the payment adjustment.

§ 416.185 Process for establishing a new class of new technology IOLs.

(a) *Announcement of deadline for requests for review.* CMS announces the deadline for each year's requests for review of a new class of new technology IOLs in the final rule updating the ASC payment rates for that calendar year.

(b) *Announcement of new classes of new technology IOLs for which review requests have been made and solicitation of public comments.* CMS announces the requests for review received in a calendar year and the deadline for public comments regarding the requests in the proposed rule updating the ASC payment rates for the following calendar

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year. The deadline for submission of public comments is 30 days following the date of the publication of the proposed rule.

(c) *Announcement of determinations regarding requests for review.* CMS announces its determinations for a calendar year in the final rule updating the ASC payment rates for the following calendar year. CMS publishes the codes and effective dates allowed for those lenses recognized by CMS as belonging to a class of new technology IOLs. New classes of new technology IOLs are effective 30 days following the date of publication of the final rule.

§ 416.190 Request for review of payment amount.

(a) *When requests can be submitted.* A request for review of the appropriateness of ASC payment for insertion of an IOL that might qualify for a payment adjustment as belonging to a new class of new technology IOLs must be submitted to CMS in accordance with the annual published deadline.

(b) *Who may submit a request.* Any individual, partnership, corporation, association, society, scientific or academic establishment, or professional or trade organization able to furnish the information required in paragraph (c) of this section may request that CMS review the appropriateness of the payment amount provided under section 1833(i)(2)(A)(iii) of the Act with respect to an IOL that meets the criteria of a new technology IOL under § 416.195.

(c) *Content of a request.* In order to be accepted by CMS for review, a request for review of the ASC payment amount for insertion of an IOL must include all the information as specified by CMS.

(d) *Confidential information.* In order for CMS to invoke the protection allowed under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and, with respect to trade secrets, the Trade Secrets Act (18 U.S.C. 1905), the requestor must clearly identify all information that is to be characterized as confidential.

§ 416.195 Determination of membership in new classes of new technology IOLs.

(a) *Factors to be considered.* CMS uses the following criteria to determine