

Centers for Medicare & Medicaid Services, HHS

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(6) For calendar year 2015, a multi-factor productivity adjustment (as determined by CMS) and 0.2 percentage point.

(7) For calendar year 2016, a multi-factor productivity adjustment (as determined by CMS), and 0.2 percentage point.

(8) For calendar year 2017, a multi-productivity adjustment (as determined by CMS) and 0.75 percentage point.

(9) For calendar year 2018, a multi-productivity adjustment (as determined by CMS) and 0.75 percentage point.

(10) For calendar year 2019, a multi-factor productivity adjustment (as determined by CMS) and 0.75 percentage point.

(11) For calendar year 2020 and subsequent years, a multifactor productivity adjustment (as determined by CMS).

(2) Beginning in calendar year 2000, CMS may substitute for the hospital inpatient market basket percentage in paragraph (b) of this section a market basket percentage increase that is determined and applied to hospital outpatient services in the same manner that the hospital inpatient market basket percentage increase is determined and applied to inpatient hospital services.

(c) *Payment rates.* The payment rate for services and procedures for which payment is made under the hospital outpatient prospective payment system is the product of the conversion factor calculated under paragraph (a) or paragraph (b) of this section and the relative weight determined under §419.31(b).

(d) *Budget neutrality.* (1) CMS adjusts the conversion factor as needed to ensure that updates and adjustments under §419.50(a) are budget neutral.

(2) In determining adjustments for 2004 and 2005, CMS will not take into account any additional expenditures per section 1833(t)(14) of the Act that would not have been made but for enactment of section 621 of the Medicare

Prescription Drug, Improvement, and Modernization Act of 2003.

[65 FR 18542, Apr. 7, 2000, as amended at 66 FR 59922, Nov. 30, 2001; 67 FR 9568, Mar. 1, 2002; 69 FR 832, Jan. 6, 2004; 75 FR 72265, Nov. 24, 2010; 76 FR 74582, Nov. 30, 2011; 77 FR 68559, Nov. 15, 2012; 78 FR 75196, Dec. 10, 2013; 79 FR 67031, Nov. 10, 2014; 80 FR 70606, Nov. 13, 2015; 81 FR 79879, Nov. 14, 2016; 82 FR 52637, Nov. 13, 2017; 82 FR 59497, Dec. 14, 2017; 83 FR 59179, Nov. 21, 2018; 85 FR 86302, Dec. 29, 2020]

EFFECTIVE DATE NOTE: At 66 FR 59922, Nov. 30, 2001, §419.32 was amended by revising paragraph (b)(1), effective Jan. 1, 2002. At 66 FR 67494, Dec. 31, 2001, paragraph (b)(1)(iii) was delayed indefinitely.

Subpart D—Payments to Hospitals

§419.40 Payment concepts.

(a) In addition to the payment rate described in §419.32, for each APC group there is a predetermined beneficiary copayment amount as described in §419.41(a). The Medicare program payment amount for each APC group is calculated by applying the program payment percentage as described in §419.41(b).

(b) For purposes of this section—

(1) Coinsurance percentage is calculated as the difference between the program payment percentage and 100 percent. The coinsurance percentage in any year is thus defined for each APC group as the greater of the following: the ratio of the APC group unadjusted copayment amount to the annual APC group payment rate, or 20 percent.

(2) Program payment percentage is calculated as the lower of the following: the ratio of the APC group payment rate minus the APC group unadjusted copayment amount, to the APC group payment rate, or 80 percent.

(3) Unadjusted copayment amount is calculated as 20 percent of the wage-adjusted national median of charges for services within an APC group furnished during 1996, updated to 1999 using an actuarial projection of charge increases for hospital outpatient department services during the period 1996 to 1999.

(c) *Limitation of copayment amount to inpatient hospital deductible amount.* The copayment amount for a procedure performed in a year cannot exceed the

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amount of the inpatient hospital deductible established under section 1813(b) of the Act for that year.

[66 FR 59922, Nov. 30, 2001]

§ 419.41 Calculation of national beneficiary copayment amounts and national Medicare program payment amounts.

(a) To calculate the unadjusted copayment amount for each APC group, CMS—

(1) Standardizes 1996 hospital charges for the services within each APC group to offset variations in hospital labor costs across geographic areas;

(2) Identifies the median of the wage-neutralized 1996 charges for each APC group; and

(3) Determines the value equal to 20 percent of the wage-neutralized 1996 median charge for each APC group and multiplies that value by an actuarial projection of increases in charges for hospital outpatient department services during the period 1996 to 1999. The result is the unadjusted beneficiary copayment amount for the APC group.

(b) CMS calculates annually the program payment percentage for every APC group on the basis of each group's unadjusted copayment amount and its payment rate after the payment rate is adjusted in accordance with § 419.32.

(c) To determine payment amounts due for a service paid under the hospital outpatient prospective payment system, CMS makes the following calculations:

(1) Makes the wage index adjustment in accordance with § 419.43.

(2) Subtracts the amount of the applicable Part B deductible provided under § 410.160 of this chapter.

(3) Multiplies the remainder by the program payment percentage for the group to determine the preliminary Medicare program payment amount.

(4) Subtracts the program payment amount from the amount determined in paragraph (c)(2) of this section to determine the copayment amount.

(i) The copayment amount for an APC cannot exceed the amount of the inpatient hospital deductible, established in accordance with § 409.82 of this chapter, for that year. For purposes of this paragraph (c)—

(A) Effective for drugs and biologicals furnished on or after January 1, 2001, the copayment amount for multiple APCs for a single drug or biological furnished on the same day will be aggregated and treated as the copayment amount for one APC.

(B) Effective for drugs and biologicals furnished on or after July 1, 2001, the copayment amount for the APC or APCs for a drug or biological furnished on the same day will be aggregated with the copayment amount for the APC that reflects the administration of the drug or biological furnished on that day and treated as the copayment amount for one APC.

(ii) Effective for services furnished from April 1, 2001 through December 31, 2001, the national unadjusted coinsurance rate for an APC cannot exceed 57 percent of the prospective payment rate for that APC.

(iii) The national unadjusted coinsurance rate for an APC cannot exceed 55 percent in calendar years 2002 and 2003; 50 percent in calendar year 2004; 45 percent in calendar year 2005; and 40 percent in calendar year 2006 and thereafter.

(iv) The copayment amount is computed as if the adjustment under §§ 419.43(d) and (e) (and any adjustments made under § 419.43(f) in relation to these adjustments) and § 419.43(h) had not been paid.

(5) Adds the amount by which the copayment amount would have exceeded the inpatient hospital deductible for that year to the preliminary Medicare program payment amount determined in paragraph (c)(3) of this section to determine the final Medicare program payment amount.

[65 FR 18542, Apr. 7, 2000, as amended at 65 FR 67829, Nov. 13, 2000; 66 FR 59923, Nov. 30, 2001; 73 FR 68814, Nov. 18, 2008]

§ 419.42 Hospital election to reduce coinsurance.

(a) A hospital may elect to reduce coinsurance for any or all APC groups on a calendar year basis. A hospital may not elect to reduce copayment amounts for some, but not all, services within the same group.

(b) A hospital must notify its fiscal intermediary of its election to reduce coinsurance no later than—

(1) June 1, 2000, for coinsurance elections for the period July 1, 2000 through December 31, 2000; or

(2) December 1 preceding the beginning of each subsequent calendar year.

(c) The hospital's election must be properly documented. It must specifically identify the APCs to which it applies and the copayment amount (within the limits identified below) that the hospital has selected for each group.

(d) The election of reduced coinsurance remains in effect unchanged during the year for which the election was made.

(e) In electing reduced coinsurance, a hospital may elect a copayment amount that is less than that year's wage-adjusted copayment amount for the group but not less than 20 percent of the APC payment rate as determined under § 419.32 or, in the case of payments calculated under § 419.43(h), not less than 20 percent of the APC payment rate as determined under § 419.43(h).

(f) The hospital may advertise and otherwise disseminate information concerning the reduced level of coinsurance that it has elected. All advertisements and information furnished to Medicare beneficiaries must specify that the coinsurance reductions advertised apply only to the specified services of that hospital and that coinsurance reductions are available only for hospitals that choose to reduce coinsurance for hospital outpatient services and are not allowed in any other ambulatory settings or physician offices.

[65 FR 18542, Apr. 7, 2000, as amended at 65 FR 67829, Nov. 13, 2000; 66 FR 59923, Nov. 30, 2001; 73 FR 68814, Nov. 18, 2008]

§ 419.43 Adjustments to national program payment and beneficiary copayment amounts.

(a) *General rule.* CMS determines national prospective payment rates for hospital outpatient department services and determines a wage adjustment factor to adjust the portion of the APC payment and national beneficiary copayment amount attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner.

(b) *Labor-related portion of payment and copayment rates for hospital outpatient services.* CMS determines the portion of hospital outpatient costs attributable to labor and labor-related costs (known as the "labor-related portion" of hospital outpatient costs) in accordance with § 419.31(c)(1).

(c) *Wage index factor.* (1) CMS uses the hospital inpatient prospective payment system wage index established in accordance with Part 412 of this chapter to make the adjustment specified under paragraph (a) of this section.

(2) For services furnished beginning January 1, 2011, the wage index factor provided for in paragraph (c)(1) of this section applicable to any hospital outpatient department that is located in a frontier State, as defined in § 412.64(m) of this chapter, may not be less than 1.00.

(3) The additional payments made under the provisions of paragraph (c)(2) of this section are not implemented in a budget neutral manner.

(d) *Outlier adjustment—(1) General rule.* Subject to paragraph (d)(4) of this section, CMS provides for an additional payment for a hospital outpatient service (or group of services) not excluded under paragraph (f) of this section for which a hospital's charges, adjusted to cost, exceed the following:

(i) A fixed multiple of the sum of—

(A) The applicable Medicare hospital outpatient payment amount determined under § 419.32(c), as adjusted under § 419.43 (other than for adjustments under this paragraph (d) or paragraph (e) of this section); and

(B) Any transitional pass-through payment under § 419.66.

(ii) At the option of CMS, a fixed dollar amount.

(2) *Amount of adjustment.* The amount of the additional payment under paragraph (d)(1) of this section is determined by CMS and approximates the marginal cost of care beyond the applicable cutoff point under paragraph (d)(1) of this section.

(3) *Limit on aggregate outlier adjustments—(i) In general.* The total of the additional payments made under this paragraph (d) for covered hospital outpatient department services furnished in a year (as estimated by CMS before

the beginning of the year) may not exceed the applicable percentage specified in paragraph (d)(3)(ii) of this section of the total program payments (sum of both the Medicare and beneficiary payments to the hospital) estimated to be made under this part for all hospital outpatient services furnished in that year. If this paragraph is first applied to less than a full year, the limit applies only to the portion of the year.

(ii) *Applicable percentage.* For purposes of paragraph (d)(3)(i) of this section, the term “applicable percentage” means a percentage specified by CMS up to (but not to exceed)—

(A) For a year (or portion of a year) before 2004, 2.5 percent; and

(B) For 2004 and thereafter, 3.0 percent.

(4) *Transitional authority.* In applying paragraph (d)(1) of this section for hospital outpatient services furnished before January 1, 2002, CMS may—

(i) Apply paragraph (d)(1) of this section to a bill for these services related to an outpatient encounter (rather than for a specific service or group of services) using hospital outpatient payment amounts and transitional pass-through payments covered under the bill; and

(ii) Use an appropriate cost-to-charge ratio for the hospital or CMHC (as determined by CMS), rather than for specific departments within the hospital.

(5) *Cost-to-charge ratios for calculating charges adjusted to cost.* For hospital outpatient services (or groups of services) as defined in paragraph (d)(1) of this section performed on or after January 1, 2009—

(i) CMS may specify an alternative to the overall ancillary cost-to-charge ratio otherwise applicable under paragraph (d)(5)(ii) of this section. A hospital may also request that its Medicare contractor use a different (higher or lower) cost-to-charge ratio based on substantial evidence presented by the hospital. Such a request must be approved by the CMS.

(ii) The overall ancillary cost-to-charge ratio applied at the time a claim is processed is based on either the most recent settled cost report or the most recent tentative settled cost

report, whichever is from the latest cost reporting period.

(iii) The Medicare contractor may use a statewide average cost-to-charge ratio if it is unable to determine an accurate overall ancillary cost-to-charge ratio for a hospital in one of the following circumstances:

(A) A new hospital that has not yet submitted its first Medicare cost report. (For purposes of this paragraph, a new hospital is defined as an entity that has not accepted assignment of an existing hospital’s provider agreement in accordance with § 489.18 of this chapter.)

(B) A hospital whose overall ancillary cost-to-charge ratio is in excess of 3 standard deviations above the corresponding national geometric mean. This mean is recalculated annually by CMS and published in the annual notice of prospective payment rates issued in accordance with § 419.50(a).

(C) Any other hospital for whom accurate data to calculate an overall ancillary cost-to-charge ratio are not available to the Medicare contractor.

(6) *Reconciliation.* For hospital outpatient services furnished during cost reporting periods beginning on or after January 1, 2009—

(i) Any reconciliation of outlier payments will be based on an overall ancillary cost-to-charge ratio calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the service is settled.

(ii) At the time of any reconciliation under paragraph (d)(6)(i) of this section, outlier payments may be adjusted to account for the time value of any underpayments or overpayments. Any adjustment will be based on a widely available index to be established in advance by CMS, and will be applied from the midpoint of the cost reporting period to the date of reconciliation.

(7) *Community mental health center (CMHC) outlier payment cap.* Outlier payments made to CMHCs for services provided on or after January 1, 2017 are subject to a cap, applied at the individual CMHC level, so that each CMHC’s total outlier payments for the calendar year do not exceed 8 percent

of that CMHC's total per diem payments for the calendar year. Total per diem payments are total Medicare per diem payments plus the total beneficiary share of those per diem payments.

(e) *Budget neutrality.* CMS establishes payment under paragraph (d) of this section in a budget-neutral manner excluding services and groups specified in paragraph (f) of this section.

(f) *Excluded services and groups.* The following services or groups are excluded from qualification for the payment adjustment under paragraph (d)(1) of this section:

(1) Drugs and biologicals that are paid under a separate APC; and

(2) Items and services paid at charges adjusted to costs by application of a hospital-specific cost-to-charge ratio.

(g) *Payment adjustment for certain rural hospitals—(1) General rule.* CMS provides for additional payment for covered hospital outpatient services not excluded under paragraph (g)(4) of this section, furnished on or after January 1, 2006, if the hospital—

(i) Is a sole community hospital under §412.92 of this chapter or is an essential access community hospital under §412.109 of this chapter; and

(ii) Is located in a rural area as defined in §412.64(b) of this chapter or is treated as being located in a rural area under §412.103 of this chapter.

(2) *Amount of adjustment.* The amount of the additional payment under paragraph (g)(1) of this section is determined by CMS and is based on the difference between costs incurred by hospitals that meet the criteria in paragraphs (g)(1)(i) and (g)(1)(ii) of this section and costs incurred by hospitals located in urban areas.

(3) *Budget neutrality.* CMS establishes the payment adjustment under paragraph (g)(2) of this section in a budget neutral manner, excluding services and groups specified in paragraph (g)(4) of this section.

(4) *Excluded services and groups.* The following services or groups are excluded from qualification for the payment adjustment in paragraph (g)(2) of this section:

(i) Drugs and biologicals that are paid under a separate APC;

(ii) Devices paid under 419.66; and

(iii) Items and services paid at charges adjusted to costs by application of a hospital-specific cost-to-charge ratio.

(5) *Copayment.* The payment adjustment in paragraph (g)(2) of this section is applied before calculating copayment amounts.

(6) *Outliers.* The payment adjustment in paragraph (g)(2) of this section is applied before calculating outlier payments.

(h) *Applicable adjustments to conversion factor for CY 2009 and for subsequent calendar years—(1) General rule.* For CY 2009 and for subsequent calendar years, the applicable adjustment to the conversion factor specified in §419.32(b)(1)(iv) is reduced by 2.0 percentage points for any hospital that fails to meet the standards for reporting of hospital outpatient quality measures as established by the Secretary for the corresponding calendar year.

(2) *Limitation.* Any reduction to a hospital's adjustment to its conversion factor specified in §419.32(b)(1)(iv) which occurs as a result of paragraph (h)(1) of this section will apply only to the calendar year involved and will not be taken into account in computing that hospital's applicable adjustment for a subsequent calendar year.

(3) *Budget neutrality.* For CY 2009 and for each subsequent calendar year, CMS makes an adjustment to the conversion factor, so that estimated aggregate payments under the OPPIs for such calendar year are not affected by any reductions to hospital adjustments which occur as a result of paragraph (h)(1) of this section.

(4) *Beneficiary copayment.* The beneficiary copayment for services to which the adjustment to the conversion factor specified under paragraph (h)(1) of this section applies is the product of the national beneficiary copayment amount calculated under §419.41 and the ratio of the adjusted conversion factor calculated under paragraph (h)(1) of this section divided by the conversion factor specified under §419.32(b)(1).

(i) *Payment adjustment for certain cancer hospitals—(1) General rule.* CMS provides for a payment adjustment for

covered hospital outpatient department services furnished on or after January 1, 2012, by a hospital described in section 1886(d)(1)(B)(v) of the Act.

(2) *Amount of payment adjustment.* The amount of the payment adjustment under paragraph (i)(1) of this section is determined by the Secretary as follows:

(i) If a hospital described in section 1886(d)(1)(B)(v) of the Act has a payment-to-cost ratio (PCR) before the cancer hospital payment adjustment (as determined by the Secretary at cost report settlement) that is less than the weighted average PCR of other hospitals furnishing services under section 1833(t) of the Act (as determined by the Secretary at the time of the applicable CY Hospital Outpatient Prospective Payment System/Ambulatory Surgical Center final rule with comment period) (referred to as the Target PCR), for covered hospital outpatient department services, the aggregate payment amount provided at cost report settlement to such hospital is equal to the amount needed to make the hospital's PCR at cost report settlement (as determined by the Secretary) equal to the target PCR (as determined by the Secretary).

(ii) If a hospital described in section 1886(d)(1)(B)(v) of the Act has a payment-to-cost ratio (PCR) before the cancer hospital payment adjustment (as determined by the Secretary at cost report settlement) that is greater than the weighted average PCR of other hospitals furnishing services under section 1833(t) of the Act (as determined by the Secretary at the time of the applicable CY Hospital Outpatient Prospective Payment System/Ambulatory Surgical Center final rule with comment period) (referred to as the Target PCR), for covered hospital outpatient department services, the aggregate payment amount provided at cost report settlement to such hospital is equal to zero.

(3) *Budget neutrality.* CMS establishes the payment adjustment under paragraph (i)(1) of this section in a budget neutral manner.

(j) *Additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators—(1) General rule.* For cost reporting periods beginning on or after

January 1, 2023, CMS provides for a payment adjustment for the additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators as described in paragraph (j)(2) of this section.

(2) *Amount of adjustment.* The payment adjustment is based on the estimated difference in the reasonable cost incurred by the hospital for domestic National Institute for Occupational Safety and Health approved surgical N95 respirators purchased during the cost reporting period as compared to other National Institute for Occupational Safety and Health approved surgical N95 respirators purchased during the cost reporting period.

(3) *Budget neutrality.* CMS establishes the payment adjustment under paragraph (j)(2) of this section in a budget neutral manner.

[65 FR 18542, Apr. 7, 2000, as amended at 65 FR 47677, Aug. 3, 2000; 66 FR 55856, Nov. 2, 2001; 69 FR 832, Jan. 6, 2004; 70 FR 68727, Nov. 10, 2005; 70 FR 76178, Dec. 23, 2005; 71 FR 68227, Nov. 24, 2006; 72 FR 66932, Nov. 27, 2007; 73 FR 68814, Nov. 18, 2008; 75 FR 72265, Nov. 24, 2010; 76 FR 74583, Nov. 30, 2011; 81 FR 79879, Nov. 14, 2016; 87 FR 72291, Nov. 23, 2022]

§ 419.44 Payment reductions for procedures.

(a) *Multiple surgical procedures.* When more than one surgical procedure for which payment is made under the hospital outpatient prospective payment system is performed during a single surgical encounter, the Medicare program payment amount and the beneficiary copayment amount are based on—

(1) The full amounts for the procedure with the highest APC payment rate; and

(2) One-half of the full program and the beneficiary payment amounts for all other covered procedures.

(b) *Interrupted procedures.* (1) Subject to the provisions of paragraph (b)(2) of this section, when a procedure 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 copayment amount are based on—

(i) The full program and beneficiary copayment 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 the full program and the beneficiary copayment amounts if the procedure for which anesthesia is planned is discontinued after the patient is prepared and taken to the room where the procedure is to be performed but before anesthesia is induced; or

(iii) One-half of the full program and beneficiary copayment amounts if a procedure for which anesthesia is not planned is discontinued after the patient is prepared and taken to the room where the procedure is to be performed.

(2) For all device-intensive procedures (defined as having a device offset of greater than 40 percent), the device offset portion of the device-intensive procedure payment is subtracted prior to determining the program payment and beneficiary copayment amounts identified in paragraph (b)(1)(ii) of this section.

[65 FR 18542, Apr. 7, 2000, as amended at 72 FR 66933, Nov. 27, 2007; 80 FR 70606, Nov. 13, 2015; 81 FR 79879, Nov. 14, 2016]

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

(a) *General rule.* CMS reduces the amount of payment for an implanted device made under the hospital outpatient prospective payment system in accordance with §419.66 for which CMS determines that a significant portion of the payment is attributable to the cost of an implanted device, when one of the following situations occur:

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

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

(3) The provider 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 APC payment.* (1) The amount of the reduction to the APC payment made under paragraphs (a)(1) and (2) of this section is calculated as the lesser of the device

offset amount that would be applied if the device implanted during a procedure assigned to the APC had transitional pass-through status under §419.66 or the amount of the credit described in paragraph (a)(2) of this section.

(2) The amount of the reduction to the APC payment made under paragraph (a)(3) of this section is calculated as the lesser of the device offset amount that would be applied if the device implanted during a procedure assigned to the APC had transitional pass-through status under §419.66 or the amount of the credit described in paragraph (a)(3) of this section.

(c) *Amount of beneficiary copayment.* The beneficiary copayment is calculated based on the APC payment after application of the reduction under paragraph (b) of this section.

[71 FR 68228, Nov. 24, 2006, as amended at 72 FR 66933, Nov. 27, 2007; 85 FR 86302, Dec. 29, 2020]

§419.46 Participation, data submission, and validation requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

(a) *Statutory authority.* Section 1833(t)(17) of the Act authorizes the Secretary to implement a quality reporting program in a manner so as to provide for a 2.0 percentage point reduction in the OPD fee schedule increase factor for a subsection (d) hospital (as defined in section 1886(d)(1)(B)) that does not submit data required to be submitted on measures in accordance with the Secretary's requirements in this part.

(b) *Participation in the Hospital OQR Program.* To participate in the Hospital OQR Program, a hospital as defined in section 1886(d)(1)(B) of the Act and is paid under the OPPS must—

(1) Register on the QualityNet website before beginning to report data;

(2) Identify and register a QualityNet security official as part of the registration process under paragraph (b)(1) of this section; and

(3) Submit at least one data element.

(c) *Withdrawal from the Hospital OQR Program.* A participating hospital may

withdraw from the Hospital OQR Program by submitting to CMS a withdrawal form that can be found in the secure portion of the QualityNet website. The hospital may withdraw any time up to and including August 31 of the year prior to the affected annual payment updates. A withdrawn hospital will not be able to later sign up to participate in that payment update, is subject to a reduced annual payment update as specified under paragraph (i) of this section, and is required to renew participation as specified in paragraph (b) of this section in order to participate in any future year of the Hospital OQR Program.

(d) *Submission of Hospital OQR Program data.* (1) *General rule.* Except as provided in paragraph (e) of this section, hospitals that participate in the Hospital OQR Program must submit to CMS data on measures selected under section 1833(t)(17)(C) of the Act in a form and manner, and at a time, specified by CMS. Hospitals sharing the same CCN must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes.

(2) *Submission deadlines.* Submission deadlines by measure and by data type are posted on the QualityNet website. All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order are extended to the first day thereafter which is not a Saturday, Sunday, or legal holiday or any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order.

(3) *Initial submission deadlines for a hospital that did not participate in the previous year's Hospital OQR Program.*

(i) Hospitals that did not participate in the previous year's Hospital OQR Program must initially submit data beginning with encounters occurring during the first calendar quarter of the year prior to the affected annual payment update.

(ii) Hospitals that did not participate in the previous year's Hospital OQR Program must follow data submission deadlines as specified in paragraph (d)(2) of this section.

(iii) Hospitals with a Medicare acceptance date before or after January 1 of the year prior to an affected annual payment update must follow data submission deadlines as specified in paragraph (d)(2) of this section.

(4) *Review and corrections period.* For both chart-abstracted and web-based measures, hospitals have a review and corrections period, which runs concurrently with the data submission period. During this timeframe, hospitals can enter, review, and correct data submitted. However, after the submission deadline, this data cannot be changed.

(e) *Exception.* CMS may grant an exception to one or more data submission deadlines and requirements in the event of extraordinary circumstances beyond the control of the hospital, such as when an act of nature affects an entire region or locale or a systemic problem with one of CMS' data collection systems directly or indirectly affects data submission. CMS may grant an exception as follows:

(1) *Upon request by the hospital.* Specific requirements for submission of a request for an exception are available on the QualityNet Web site.

(2) *At the discretion of CMS.* CMS may grant exceptions to hospitals that have not requested them when CMS determines that an extraordinary circumstance has occurred.

(f) *Validation of Hospital OQR Program data.* CMS may validate one or more measures selected under section 1833(t)(17)(C) of the Act by reviewing documentation of patient encounters submitted by selected participating hospitals.

(1) Upon written request by CMS or its contractor, a hospital must submit to CMS supporting medical record documentation that the hospital used for purposes of data submission under the program. The specific sample that a hospital must submit will be identified in the written request. A hospital must submit the supporting medical record documentation to CMS or its contractor within 30 days of the date identified on the written request, in the form and manner specified in the written request.

(2) A hospital meets the validation requirement with respect to a calendar year if it achieves at least a 75-percent

reliability score, as determined by CMS.

(3) CMS will select a random sample of 450 hospitals for validation purposes, and will select an additional 50 hospitals for validation purposes based on the following criteria:

(i) The hospital fails the validation requirement that applies to the previous year's payment determination; or

(ii) The hospital has an outlier value for a measure based on the data it submits. An "outlier value" is a measure value that is greater than 5 standard deviations from the mean of the measure values for other hospitals, and indicates a poor score; or

(iii) Any hospital that has not been randomly selected for validation in any of the previous 3 years; or

(iv) Any hospital that passed validation in the previous year but had a two-tailed confidence interval that included 75 percent; or

(v) Any hospital with a two-tailed confidence interval that is less than 75 percent, and that had less than four quarters of data due to receiving an extraordinary circumstance exception (ECE) for one or more quarters.

(4) Hospitals that are selected and receive a score for validation of chart-abstracted measures may request an educational review in order to better understand the results within 30 calendar days from the date the validation results are made available. If the results of an educational review indicate that a hospital's medical records selected for validation for chart-abstracted measures was incorrectly scored, the corrected quarterly validation score will be used to compute the hospital's final validation score at the end of the calendar year.

(g) *Reconsiderations and appeals of Hospital OQR Program decisions.* (1) A hospital may request reconsideration of a decision by CMS that the hospital has not met the requirements of the Hospital OQR Program in paragraph (b) of this section for a particular calendar year. Except as provided in paragraph (e) of this section, a hospital must submit a reconsideration request to CMS via the QualityNet website, no later than March 17, or if March 17 falls on a nonwork day, on the first day after March 17 which is not a nonwork day

as defined in paragraph (d)(2) of this section, of the affected payment year as determined using the date the request was mailed or submitted to CMS.

(2) A reconsideration request must contain the following information:

(i) The hospital's CMS Certification Number (CCN);

(ii) The name of the hospital;

(iii) The CMS-identified reason for not meeting the requirements of the affected payment year's Hospital OQR Program as provided in any CMS notification to the hospital;

(iv) The hospital's basis for requesting reconsideration. The hospital must identify its specific reason(s) for believing it should not be subject to the reduced annual payment update;

(v) The hospital-designated personnel contact information, including name, email address, telephone number, and mailing address (must include physical mailing address, not just a post office box);

(vi) The hospital-designated personnel's signature;

(vii) A copy of all materials that the hospital submitted to comply with the requirements of the affected Hospital OQR Program payment determination year; and

(viii) If the hospital is requesting reconsideration on the basis that CMS determined it did not meet the affected payment determination year's validation requirement set forth in paragraph (f)(1) of this section, the hospital must provide a written justification for each appealed data element classified during the validation process as a mismatch. Only data elements that affect a hospital's validation score are eligible to be reconsidered.

(3) A hospital that is dissatisfied with a decision made by CMS on its reconsideration request may file an appeal with the Provider Reimbursement Review Board under part 405, subpart R, of this chapter.

(h) *Requirements for Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey.* OAS CAHPS is the Outpatient and Ambulatory Surgical Center Consumer Assessment of Healthcare Providers and Systems Survey that measures patient experience

of care after a recent surgery or procedure at either a hospital outpatient department or an ambulatory surgical center. Hospital outpatient departments must use an approved OAS CAHPS survey vendor to administer and submit OAS CAHPS data to CMS.

(1) [Reserved]

(2) CMS approves an application for an entity to administer the OAS CAHPS Survey as a vendor on behalf of one or more hospital outpatient departments when the applicant has met the Minimum Survey Requirements and Rules of Participation that can be found on the official OAS CAHPS website, and agrees to comply with the current survey administration protocols that can be found on the official OAS CAHPS Survey website. An entity must be an approved OAS CAHPS Survey vendor in order to administer and submit OAS CAHPS Survey data to CMS on behalf of one or more hospital outpatient departments.

(i) *Retention and removal of quality measures under the Hospital OQR Program*—(1) *General rule for the retention of quality measures.* Quality measures adopted for the Hospital OQR Program measure set for a previous payment determination year are retained for use in subsequent payment determination years, except when they are removed, suspended, or replaced as set forth in paragraphs (i)(2) and (3) of this section.

(2) *Immediate measure removal.* For cases in which CMS believes that the continued use of a measure as specified raises patient safety concerns, CMS will immediately remove a quality measure from the Hospital OQR Program and will promptly notify hospitals and the public of the removal of the measure and the reasons for its removal through the Hospital OQR Program ListServ and the QualityNet website.

(3) *Measure removal, suspension, or replacement through the rulemaking process.* Unless a measure raises specific safety concerns as set forth in paragraph (i)(2) of this section, CMS will use the regular rulemaking process to remove, suspend, or replace quality measures in the Hospital OQR Program to allow for public comment.

(i) *Factors for consideration of removal of quality measures.* CMS will weigh

whether to remove measures based on the following factors:

(A) *Factor 1.* Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (“topped out” measures);

(B) *Factor 2.* Performance or improvement on a measure does not result in better patient outcomes;

(C) *Factor 3.* A measure does not align with current clinical guidelines or practice;

(D) *Factor 4.* The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic;

(E) *Factor 5.* The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;

(F) *Factor 6.* The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic;

(G) *Factor 7.* Collection or public reporting of a measure leads to negative unintended consequences other than patient harm; and

(H) *Factor 8.* The costs associated with a measure outweigh the benefit of its continued use in the program.

(ii) *Criteria to determine topped-out measures.* For the purposes of the Hospital OQR Program, a measure is considered to be topped-out under paragraph (i)(3)(i)(A) of this section when it meets both of the following criteria:

(A) Statistically indistinguishable performance at the 75th and 90th percentiles (defined as when the difference between the 75th and 90th percentiles for a hospital’s measure is within two times the standard error of the full data set); and

(B) A truncated coefficient of variation less than or equal to 0.10.

(iii) *Application of measure removal factors.* The benefits of removing a measure from the Hospital OQR Program will be assessed on a case-by-case basis. Under this case-by-case approach, a measure will not be removed

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solely on the basis of meeting any specific factor.

[78 FR 75196, Dec. 10, 2013, as amended at 79 FR 67031, Nov. 10, 2014; 80 FR 70606, Nov. 13, 2015; 81 FR 79879, Nov. 14, 2016; 82 FR 52637, Nov. 13, 2017; 82 FR 59497, Dec. 14, 2017; 83 FR 59179, Nov. 21, 2018; 85 FR 86302, Dec. 29, 2020; 86 FR 63993, Nov. 16, 2021; 87 FR 72291, Nov. 23, 2022]

§ 419.47 Coding and Payment for Category B Investigational Device Exemption (IDE) Studies.

(a) *Creation of a new HCPCS code for Category B IDE Studies.* CMS will create a new HCPCS code, or revise an existing HCPCS code, to describe a Category B IDE study, which will include both the treatment and control arms, related device(s) of the study, as well as routine care items and services, as specified under § 405.201 of this chapter, when CMS determines that:

(1) The Medicare coverage IDE study criteria in § 405.212 of this chapter are met; and

(2) A new or revised code is necessary to preserve the scientific validity of such a study, such as by preventing the unblinding of the study.

(b) *Payment for Category B IDE Studies.* Where CMS creates a new HCPCS code or revises an existing HCPCS code under paragraph (a) of this section, CMS will:

(1) Make a single packaged payment for the HCPCS code that includes payment for the investigational device, placebo control, and routine care items and services of a Category B IDE study, as specified under § 405.201 of this chapter; and

(2) Calculate the single packaged payment rate for the HCPCS code based on the average resources utilized for each study participant, including the frequency with which the investigational device is used in the study population.

[87 FR 72291, Nov. 23, 2022]

§ 419.48 Definition of excepted items and services.

(a) Excepted items and services are items or services that are furnished on or after January 1, 2017—

(1) By a dedicated emergency department (as defined at § 489.24(b) of this chapter); or

(2) By an excepted off-campus provider-based department defined in paragraph (b) of this section that has not impermissibly relocated or changed ownership.

(b) For the purpose of this section, “excepted off-campus provider-based department” means a “department of a provider” (as defined at § 413.65(a)(2) of this chapter) that is located on the campus (as defined in § 413.65(a)(2) of this chapter) or within the distance described in such definition from a “remote location of a hospital” (as defined in § 413.65(a)(2) of this chapter) that meets the requirements for provider-based status under § 413.65 of this chapter. This definition also includes an off-campus department of a provider that was furnishing services prior to November 2, 2015 that were billed under the OPPS in accordance with timely filing limits.

(c) Payment for items and services that do not meet the definition in paragraph (a) of this section will generally be made under the Medicare Physician Fee Schedule on or after January 1, 2017.

[81 FR 79880, Nov. 14, 2016; 82 FR 36, Jan. 3, 2017]

Subpart E—Updates

§ 419.50 Annual review.

(a) *General rule.* Not less often than annually, CMS reviews and updates groups, relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

(b) *Consultation requirement.* CMS will consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise CMS concerning) the clinical integrity of the groups and weights. The panel may use data collected or developed by entities and organizations (other than the Department of Health and Human Services) in conducting the review.

(c) *Effective dates.* CMS conducts the first annual review under paragraph (a) of this section in 2001 for payments made in 2002.