

§§ 425.661–425.669 [Reserved]

EFFECTIVE DATE NOTE: At 89 FR 79171, Sept. 27, 2024, §§ 425.661 through 425.669 were added and reserved, effective Oct. 15, 2024.

§ 425.670 Adjustments to mitigate the impact of significant, anomalous, and highly suspect billing activity on Shared Savings Program financial calculations involving calendar year 2023.

(a) *General.* This section describes adjustments CMS makes to Shared Savings Program calculations to mitigate the impact of significant, anomalous, and highly suspect billing activity occurring in calendar year 2023.

(b) *Significant, anomalous, and highly suspect billing activity for a HCPCS or CPT code impacting Shared Savings Program calculations.* CMS has determined that the billing of the following HCPCS codes represents significant, anomalous, and highly suspect billing activity for calendar year 2023 that warrants adjustment—

(1) A4352 (Intermittent urinary catheter; Coude (curved) tip, with or without coating (Teflon, silicone, silicone elastomeric, or hydrophilic, etc.), each); and

(2) A4353 (Intermittent urinary catheter, with insertion supplies).

(c) *Applicability of adjustments to performance year and benchmark year calculations.* Notwithstanding any other provision in this part, CMS adjusts the following Shared Savings Program calculations, as applicable, to exclude all Medicare Parts A and B fee-for-service payment amounts on DMEPOS claims (claim types 72 and 82) associated with a HCPCS code specified in paragraph (b) of this section for the period specified in paragraph (d) of this section:

(1) Calculation of Medicare Parts A and B fee-for-service expenditures for an ACO's assigned beneficiaries for all purposes including the following: Establishing, adjusting, updating, and resetting the ACO's historical benchmark and determining performance year expenditures.

(2) Calculation of fee-for-service expenditures for assignable beneficiaries as used in determining county-level fee-for-service expenditures and national Medicare fee-for-service expendi-

tures, including the following calculations:

(i) Determining average county fee-for-service expenditures based on expenditures for the assignable population of beneficiaries in each county in the ACO's regional service area according to §§ 425.601(c) and 425.654(a) for purposes of calculating the ACO's regional fee-for-service expenditures.

(ii) Determining the 99th percentile of national Medicare fee-for-service expenditures for assignable beneficiaries for purposes of the following:

(A) Truncating assigned beneficiary expenditures used in calculating benchmark expenditures under § 425.652(a)(4), and performance year expenditures under §§ 425.605(a)(3) and 425.610(a)(4).

(B) Truncating expenditures for assignable beneficiaries in each county for purposes of determining county fee-for-service expenditures according to §§ 425.601(c)(3) and 425.654(a)(3).

(C) Truncating expenditures for assignable beneficiaries for purposes of determining truncated national per capita fee-for service expenditures for purposes of calculating the ACPT according to § 425.660(b)(3).

(iii) Determining truncated national per capita fee-for-service Medicare expenditures for assignable beneficiaries for purposes of calculating the ACPT according to § 425.660(b)(3).

(iv) Determining national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program for assignable beneficiaries for purposes of capping the regional adjustment to the ACO's historical benchmark according to § 425.656(c)(3) and capping the prior savings adjustment according to § 425.658(c)(1)(ii).

(v) Determining national growth rates that are used as part of the blended growth rates used to trend forward BY1 and BY2 expenditures to BY3 according to § 425.652(a)(5)(ii) and as part of the blended growth rates used to update the benchmark according to §§ 425.601(b)(2) and 425.652(b)(2)(i).

(3) Calculation of Medicare Parts A and B fee-for-service revenue of ACO participants for purposes of calculating the ACO's loss recoupment limit under the BASIC track as specified in § 425.605(d).

(4) Calculation of total Medicare Parts A and B fee-for-service revenue of ACO participants and total Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries for purposes of identifying whether an ACO is a high revenue ACO or low revenue ACO, as defined under § 425.20, and determining an ACO's eligibility to receive advance investment payments according to § 425.630.

(5) Calculation or recalculation of the amount of the ACO's repayment mechanism arrangement according to § 425.204(f)(4).

(d) *Period of adjustment.* CMS adjusts the Shared Savings Program calculations specified in paragraph (c) of this section for significant, anomalous, and highly suspect billing activity identified pursuant to paragraph (b) of this section for calendar year 2023, when calendar year 2023 is either a performance year or a benchmark year.

(e) *Adjustments for growth rates used in calculating the ACPT.* In addition to adjustments described in paragraph (c) of this section, CMS makes adjustments for payments associated with a HCPCS code specified in paragraph (b) of this section for BY3 in projecting per capita growth in Parts A and B fee-for-service expenditures, according to § 425.660(b)(1), for purposes of calculating the ACPT for agreement periods beginning on January 1, 2024.

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Subpart H—Data Sharing With ACOs

§ 425.700 General rules.

(a) CMS shares aggregate reports with the ACO.

(b) CMS shares beneficiary identifiable data with ACOs on the condition that the ACO, its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to the ACO's activities observe all relevant statutory and regulatory provisions regarding the appropriate use of data and the confidentiality and privacy of individually identifiable health information

and comply with the terms of the data use agreement described in this subpart.

(c) The ACO must not limit or restrict appropriate sharing of medical record data with providers and suppliers both within and outside the ACO in accordance with applicable law.

§ 425.702 Aggregate reports.

CMS shares aggregate reports with ACOs as follows:

(a) Aggregate reports are shared at the start of the agreement period based on beneficiary claims data used to calculate the benchmark, and each quarter thereafter during the agreement period.

(b) These aggregate reports include, when available, the following information, deidentified in accordance with 45 CFR 164.514(b):

(1) Aggregated metrics on the assigned beneficiary population.

(2) Utilization and expenditure data at the start of the agreement period based on historical beneficiaries used to calculate the benchmark.

(c)(1)(i) For performance years 2012 through 2015, at the beginning of the agreement period, during each quarter (and in conjunction with the annual reconciliation), and at the beginning of each performance year, CMS, upon the ACO's request for the data for purposes of population-based activities relating to improving health or reducing growth in health care costs, process development, case management, and care coordination, will provide the ACO with information regarding preliminarily prospectively assigned beneficiaries whose data was used to generate the aggregate data reports under paragraphs (a) and (b) of this section. The information includes the following:

(A) Beneficiary name.

(B) Date of birth.

(C) HICN.

(D) Sex.

(ii) For performance year 2016 and subsequent performance years, at the beginning of the agreement period, during each quarter (and in conjunction with the annual reconciliation), and at the beginning of each performance year, CMS, upon the ACO's request for the data for purposes of population-

based activities relating to improving health or reducing growth in health care costs, protocol development, case management, and care coordination, provides the ACO with information about its fee-for-service population.

(A) For an ACO participating under preliminary prospective assignment with retrospective reconciliation as specified under § 425.400(a)(2), the following information is made available regarding preliminarily prospectively assigned beneficiaries and beneficiaries that received a primary care service during the previous 12 months from one of the ACO participants that submits claims for primary care services used to determine the ACO's assigned population under subpart E of this part:

- (1) Beneficiary name.
- (2) Date of birth.
- (3) Beneficiary identifier.
- (4) Sex.

(B) For an ACO participating under preliminary prospective assignment with retrospective reconciliation as specified under § 425.400(a)(2), information in the following categories, which represents the minimum data necessary for ACOs to conduct health care operations work, is made available regarding preliminarily prospectively assigned beneficiaries:

- (1) Demographic data such as enrollment status.
- (2) Health status information such as risk profile and chronic condition subgroup.
- (3) Utilization rates of Medicare services such as the use of evaluation and management, hospital, emergency, and post-acute services, including the dates and place of service.
- (4) Expenditure information related to utilization of services.

(C) The information under paragraphs (c)(1)(ii)(A) and (B) of this section is made available to ACOs participating under prospective assignment as specified under § 425.400(a)(3), but is limited to the ACO's prospectively assigned beneficiaries.

(iii) For performance year 2024 and subsequent performance years, CMS, upon the ACO's request for the data for purposes of population-based activities relating to improving health or reducing growth in health care costs, protocol development, case management,

and care coordination, provides the ACO with information about its fee-for-service population.

(A) The following information is made available to ACOs regarding beneficiaries eligible for Medicare CQMs as defined at § 425.20:

- (1) Beneficiary name.
- (2) Date of birth.
- (3) Beneficiary identifier.
- (4) Sex.

(B) Information in the following categories, which represents the minimum data necessary for ACOs to conduct health care operations work, is made available to ACOs regarding beneficiaries eligible for Medicare CQMs as defined at § 425.20:

- (1) Demographic data such as enrollment status.
- (2) Health status information such as risk profile and chronic condition subgroup.
- (3) Utilization rates of Medicare services such as the use of evaluation and management, hospital, emergency, and post-acute services, including the dates and place of service.

(2) In its request for these data, the ACO must certify that it is seeking the following information:

- (i) As a HIPAA-covered entity, and the request reflects the minimum data necessary for the ACO to conduct its own health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501.
- (ii) As the business associate of its ACO participants and ACO providers/suppliers, who are HIPAA-covered entities, and the request reflects the minimum data necessary for the ACO to conduct health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 on behalf of those participants.

(iii) As an organized health care arrangement (as defined at 45 CFR 160.103), and the request reflects the minimum data necessary for the ACO to conduct health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 on behalf of the organized health care arrangement.