

§ 425.613

(iii) CMS identifies a program integrity issue affecting the ACO's use of the waiver.

(4) CMS reserves the right to take compliance action, including termination, against an ACO for noncompliance with program rules, including misuse of a waiver under this section, as specified at §§ 425.216 and 425.218.

(e) *Other rules governing use of waivers.* (1) Waivers under this section do not protect financial or other arrangements between or among ACOs, ACO participants, ACO providers/suppliers, or other individual or entities providing services to Medicare beneficiaries from liability under the fraud and abuse laws or any other applicable laws.

(2) Waivers under this section do not protect any person or entity from liability for any violation of law or regulation for any conduct other than the conduct permitted by a waiver under paragraph (a) of this section.

(3) ACOs must ensure compliance with all claims submission requirements, except those expressly waived under paragraph (a) of this section.

(f) *Waiver for payment for telehealth services.* For performance year 2020 and subsequent performance years, CMS waives the originating site requirements in section 1834(m)(4)(C)(i) and (ii) of the Act and makes payment for telehealth services furnished to a beneficiary, if the following conditions are met:

(1) The beneficiary was prospectively assigned to an ACO that is an applicable ACO for purposes of § 425.613 at the beginning of the applicable performance year, but the beneficiary was excluded in the most recent quarterly update to the prospective assignment list under § 425.401(b).

(2) The telehealth services are provided by a physician or practitioner billing under the TIN of an ACO participant in the ACO within 90 days following the date CMS delivers the quarterly exclusion list to the ACO.

(3) But for the beneficiary's exclusion from the ACO's prospective assignment list, CMS would have made payment to

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the ACO participant for such services under § 425.613.

[80 FR 32843, June 9, 2015, as amended at 81 FR 80561, Nov. 15, 2016; 82 FR 53371, Nov. 15, 2017; 83 FR 68080, Dec. 31, 2018; 84 FR 63204, Nov. 15, 2019; 87 FR 70242, Nov. 18, 2022]

§ 425.613 Telehealth services.

(a) *General.* Payment is available for otherwise covered telehealth services furnished on or after January 1, 2020, by a physician or other practitioner billing through the TIN of an ACO participant in an applicable ACO, without regard to the geographic requirements under section 1834(m)(4)(C)(i) of the Act, in accordance with the requirements of this section.

(1) For purposes of this section:

(i) An applicable ACO is an ACO that is participating under a two-sided model under § 425.600 and has elected prospective assignment under § 425.400(a)(3) for the performance year.

(ii) The home of the beneficiary is treated as an originating site under section 1834(m)(4)(C)(ii) of the Act.

(2) For payment to be made under this section, the following requirements must be met:

(i) The beneficiary is prospectively assigned to the ACO for the performance year in which the beneficiary received the telehealth service.

(ii) The physician or practitioner who furnishes the telehealth service must bill under the TIN of an ACO participant that is included on the certified ACO participant list under § 425.118 for the performance year in which the service is rendered.

(iii) The originating site must comply with applicable State licensing requirements.

(iv) When the originating site is the beneficiary's home, the telehealth services must not be inappropriate to furnish in the home setting. Services that are typically furnished in an inpatient setting may not be furnished as a telehealth service when the originating site is the beneficiary's home.

(v) CMS does not pay a facility fee when the originating site is the beneficiary's home.

(b) *Beneficiary protections.* (1) When a beneficiary who is not prospectively assigned to an applicable ACO or in a 90-

day grace period under § 425.612(f) receives a telehealth service from a physician or practitioner billing through the TIN of an ACO participant participating in an applicable ACO, CMS makes no payment for the telehealth service to the ACO participant.

(2) In the event that CMS makes no payment for a telehealth service furnished by a physician or practitioner billing through the TIN of an ACO participant, and the only reason the claim was non-covered is because the beneficiary is not prospectively assigned to the ACO or in the 90-day grace period under § 425.612(f), all of the following beneficiary protections apply:

(i) The ACO participant must not charge the beneficiary for the expenses incurred for such service.

(ii) The ACO participant must return to the beneficiary any monies collected for such service.

(iii) The ACO may be required to submit a corrective action plan under § 425.216(b) for CMS approval. If the ACO is required to submit a corrective action plan and, after being given an opportunity to act upon the corrective action plan, the ACO fails to implement the corrective action plan or demonstrate improved performance upon completion of the corrective action plan, CMS may terminate the participation agreement as specified under § 425.216(b)(2).

(c) *Termination date for purposes of payment for telehealth services.* (1) Payment for telehealth services under paragraph (a) of this section does not extend beyond the end of the applicable ACO's participation agreement.

(2) If CMS terminates the participation agreement under § 425.218, payment for telehealth services under paragraph (a) of this section is not made with respect to telehealth services furnished beginning on the date specified by CMS in the termination notice.

(3) If the ACO terminates the participation agreement, payment for telehealth services under paragraph (a) of this section is not made with respect to telehealth services furnished beginning on the effective date of termination as specified in the written notification required under § 425.220.

(d) *Monitoring of telehealth services.* (1) CMS monitors and audits the use of telehealth services by the ACO and its ACO participants and ACO providers/suppliers, in accordance with § 425.316.

(2) CMS reserves the right to take compliance action, up to and including termination of the participation agreement, as specified in §§ 425.216 and 425.218, with respect to an applicable ACO for non-compliance with program requirements, including inappropriate use of telehealth services.

[83 FR 68081, Dec. 31, 2018]

§§ 425.614–425.629 [Reserved]

§ 425.630 Option to receive advance investment payments.

(a) *Purpose.* Advance investment payments are intended to encourage low-revenue ACOs that are inexperienced with risk to participate in the Shared Savings Program and to provide additional resources to such ACOs in order to support care improvement for underserved beneficiaries.

(b) *Eligibility.* An ACO is eligible to receive advance investment payments as specified in this section if CMS determines that all of the following criteria are met:

(1) The ACO is not a renewing or a re-entering ACO.

(2) CMS has determined that the ACO is eligible to participate in the Shared Savings Program.

(3) The ACO is inexperienced with performance-based risk Medicare ACO initiatives during its first 2 performance years and participates in the BASIC track's glide path as follows:

(i) For performance year 1, the ACO must participate in Level A of the BASIC track's glide path.

(ii) For performance year 2, the ACO may participate in Level A of the BASIC track's glide path (in accordance with § 425.600(a)(4)(i)(C)(3)) or Level B.

(iii) For performance years 3 through 5, the ACO may participate in Level A of the BASIC track's glide path (in accordance with § 425.600(a)(4)(i)(C)(3)), or Levels B through E.

(4) The ACO is a low revenue ACO.

(c) *Application procedure.* To obtain a determination regarding whether an ACO may receive advance investment

payments, the ACO must submit to CMS complete supplemental information as part of its application to participate in the Shared Savings Program (filed pursuant to § 425.202) in the form and manner and by a deadline specified by CMS.

(d) *Application contents and review.* (1) *General.* An ACO must submit to CMS supplemental application information sufficient for CMS to determine whether the ACO is eligible to receive advance investment payments. In addition, the ACO must submit a proposed spend plan as part of the supplemental application information.

(2) *Spend plan.* The spend plan must:

(i) Describe how the ACO will spend its advance investment payments during the agreement period to build care coordination capabilities (including coordination with community-based organizations, as appropriate), address specific health disparities, and meet other criteria under this section.

(ii) Identify the categories of goods and services that will be purchased with advance investment payment funds (including any allowable uses under paragraph (e) of this section), the dollar amounts to be spent on the various categories, and such other information as may be specified by CMS.

(iii) State that the ACO has established a separate designated account for the deposit and expenditure of all advance investment payments in accordance with paragraph (e)(4) of this section.

(3) *CMS review.* CMS will review the supplemental application information to determine whether an ACO meets the eligibility criteria and other requirements for advance investment payments and will approve or deny the advance investment payment application accordingly. CMS may review an ACO's spend plan at any time and require the ACO to modify its spend plan to comply with the requirements of this paragraph (d) and paragraph (e) of this section.

(e) *Use and management of advance investment payments—*(1) *Allowable uses.* An ACO must use an advance investment payment to improve the quality and efficiency of items and services furnished to beneficiaries by investing in increased staffing, health care infra-

structure, and the provision of accountable care for underserved beneficiaries, which may include addressing social determinants of health. Expenditures of advance investment payments must comply with the beneficiary incentive provision at § 425.304, paragraph (e)(2) of this section, and all other applicable laws and regulations.

(2) *Prohibited uses.* Advance investment payments may not be used for any expense other than allowable uses under paragraph (e)(1) of this section. In the case of an ACO participating in Level E of the BASIC track, the repayment of any shared losses incurred as specified in a written notice in accordance with § 425.605(e)(2).

(3) *Duration for spending payments.* An ACO may spend an advance investment payment over its entire agreement period. An ACO must repay to CMS any unspent funds remaining at the end of the ACO's agreement period, except if the ACO terminated its current participation agreement under § 425.220 at the end of performance year 2 or later and immediately enters a new agreement period to continue its participation in the Shared Savings Program, the ACO must spend its advance investment payments within 5 performance years of when it first received advance investment payments and repay to CMS any unspent funds remaining at the end of that fifth performance year.

(4) *Segregation of advance investment payments.* An ACO must segregate advance investment payments from all other revenues by establishing and maintaining a separate account into which all advance investment payments will be deposited immediately and from which all disbursements of such funds are made only for allowable uses in accordance with this paragraph.

(f) *Payment methodology.* An ACO receives two types of advance investment payments: a one-time payment of \$250,000 and quarterly payments calculated pursuant to the methodology defined in paragraph (f)(2) of this section. CMS notifies in writing each ACO of its determination of the amount of advance investment payment and the notice will inform the ACO of its right to request reconsideration review in accordance with the procedures specified in subpart I of this part. If CMS

does not make any advance investment payment, the notice will specify the reason(s) why and inform the ACO of its right to request reconsideration review in accordance with the procedures specified in subpart I of this part.

(1) *Frequency of payments.* An ACO will receive the one-time payment at the beginning of Performance Year 1 of the ACO's agreement period. An ACO will receive quarterly payments each quarter for the first two performance years of the ACO's agreement period. An ACO may receive no more than eight quarterly payments.

(2) *Quarterly payment amount calculation methodology.* CMS does all of the following in determining the quarterly payment amount prior to the start of the quarter.

(i) Determines the ACO's assigned beneficiary population. The assigned beneficiaries used in determining the quarterly payment amount are the beneficiaries most recently assigned to the ACO under § 425.400(a)(2) (for an ACO under preliminary prospective assignment with retrospective reconciliation) or § 425.400(a)(3) (for an ACO under prospective assignment), based on the certified ACO participant list for the relevant performance year.

(ii) Assigns each beneficiary a risk factors-based score. For each beneficiary in the assigned population identified

in paragraph (f)(2)(i) of this section, CMS applies the following requirements in assigning a risk factors-based score:

(A) The risk factors-based score will be set to 100 if the beneficiary is enrolled in the Medicare Part D LIS or is dually eligible for Medicare and Medicaid.

(B) The risk factors-based score will be set to the Area Deprivation Index national percentile rank matched to the beneficiary's mailing address if the beneficiary is not enrolled in the LIS or is not dually eligible for Medicare and Medicaid and sufficient data is available to match the beneficiary to an Area Deprivation Index national percentile rank.

(C) The risk factors-based score will be set to 50 if the beneficiary is not enrolled in the LIS or is not dually eligible for Medicare and Medicaid and sufficient data is not available to match the beneficiary to an Area Deprivation Index national percentile rank.

(iii) Determines a beneficiary's payment amount. For each beneficiary in the assigned population identified in paragraph (f)(2)(i) of this section, CMS determines the payment amount that corresponds to the beneficiary's risk factors-based score determined in paragraph (f)(2)(ii) of this section. The beneficiary payment amount is as follows:

TABLE 1 TO PARAGRAPH (f)(2)(iii)

Risk factors-based score	1–24	25–34	35–44	45–54	55–64	65–74	75–84	85–100
Payment amount	\$0	\$20	\$24	\$28	\$32	\$36	\$40	\$45

(iv) Calculates the ACO's quarterly payment amount. The ACO's quarterly payment amount is the sum of the beneficiary payment amounts corresponding to each assigned beneficiary's risk factors-based score, specified in paragraph (f)(2)(iii) of this section, capped at 10,000 beneficiaries. If the ACO has more than 10,000 assigned beneficiaries according to paragraph (f)(2)(i) of this section, CMS will calculate the quarterly payment amount based on the 10,000 assigned beneficiaries with the highest risk factors-

based scores determined according to paragraph (f)(2)(ii) of this section.

(g) *Recoupment and recovery of advance investment payments, and notice of bankruptcy.* (1) CMS will recoup advance investment payments made to an ACO from any shared savings the ACO earns until CMS has recouped in full the amount of advance investment payments made to the ACO. For both renewing and re-entering ACOs, CMS will carry forward any remaining balance owed to subsequent performance year(s) in which the ACO achieves