

## § 425.401

defined in § 425.20), when the assignment window includes any month(s) during the COVID-19 Public Health Emergency defined in § 400.200 of this chapter.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32840, June 9, 2015; 82 FR 53369, Nov. 15, 2017; 83 FR 60092, Nov. 23, 2018; 83 FR 68069, Dec. 31, 2018; 85 FR 27625, May 8, 2020; 85 FR 85040, Dec. 28, 2020; 86 FR 65684, Nov. 19, 2021; 87 FR 70233, Nov. 18, 2022]

### § 425.401 Criteria for a beneficiary to be assigned to an ACO.

(a) A beneficiary may be assigned to an ACO under the assignment methodology in §§ 425.402 and 425.404, for a performance or benchmark year, if the beneficiary meets all of the following criteria during the assignment window:

(1)(i) Has at least 1 month of Part A and Part B enrollment; and

(ii) Does not have any months of Part A only or Part B only enrollment.

(2) Does not have any months of Medicare group (private) health plan enrollment.

(3) Is not assigned to any other Medicare shared savings initiative.

(4) Lives in the United States or U.S. territories and possessions, based on the most recent available data in our beneficiary records regarding the beneficiary's residence at the end of the assignment window.

(b) A beneficiary is excluded from the prospective assignment list of an ACO that is participating under prospective assignment under § 425.400(a)(3) at the end of a performance or benchmark year and quarterly during each performance year consistent with § 425.400(a)(3)(ii), or at the end of CY 2019 as specified in § 425.609(b)(1)(ii) and (c)(1)(ii) if the beneficiary meets any of the following criteria during the performance or benchmark year:

(1)(i) Does not have at least 1 month of Part A and Part B enrollment; and

(ii) Has any months of Part A only or Part B only enrollment.

(2) Has any months of Medicare group (private) health plan enrollment.

(3) Did not live in the United States or U.S. territories and possessions, based on the most recent available data in our beneficiary records regard-

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ing the beneficiary's residency at the end of the year.

[80 FR 32840, June 9, 2015, as amended at 83 FR 60093, Nov. 23, 2018; 83 FR 68069, Dec. 31, 2018]

### § 425.402 Basic assignment methodology.

(a) For performance years 2012 through 2015, CMS employs the following step-wise methodology to assign Medicare beneficiaries to an ACO after identifying all patients that had at least one primary care service with a physician who is an ACO professional of that ACO:

(1)(i) Identify all primary care services rendered by primary care physicians during one of the following:

(A) The most recent 12 months (for purposes of preliminary prospective assignment and quarterly updates to the preliminary prospective assignment).

(B) The performance year (for purposes of final assignment).

(ii) The beneficiary is assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by all the primary care physicians who are ACO professionals in the ACO are greater than the allowed charges for primary care services furnished by primary care physicians who are—

(A) ACO professionals in any other ACO; and

(B) Not affiliated with any ACO and identified by a Medicare-enrolled TIN.

(2) The second step considers the remainder of the beneficiaries who have received at least one primary care service from an ACO physician, but who have not had a primary care service rendered by any primary care physician, either inside or outside the ACO. The beneficiary will be assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by all ACO professionals in the ACO are greater than the allowed charges for primary care services furnished by—

(i) All ACO professionals in any other ACO; and

(ii) Other physicians, nurse practitioners, physician assistants, clinical nurse specialists who are unaffiliated with an ACO and are identified by a Medicare-enrolled TIN.

(b) For performance year 2016 and subsequent performance years, CMS employs the following step-wise methodology to assign Medicare fee-for-service beneficiaries to an ACO based on available claims information:

(1) Identify all beneficiaries that had at least one primary care service with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in paragraph (c) of this section.

(2) Identify all primary care services furnished to beneficiaries identified in paragraph (b)(1) of this section by ACO professionals of that ACO who are primary care physicians as defined under § 425.20, non-physician ACO professionals, and physicians with specialty designations included in paragraph (c) of this section during the applicable assignment window.

(3) Under the first step, a beneficiary identified in paragraph (b)(1) of this section is assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by primary care physicians who are ACO professionals and non-physician ACO professionals in the ACO are greater than the allowed charges for primary care services furnished by primary care physicians, nurse practitioners, physician assistants, and clinical nurse specialists who are—

(i) ACO professionals in any other ACO; or

(ii) Not affiliated with any ACO and identified by a Medicare-enrolled billing TIN.

(4) The second step considers the remainder of the beneficiaries identified in paragraph (b)(1) of this section who have not had a primary care service rendered by any primary care physician, nurse practitioner, physician assistant, or clinical nurse specialist, either inside the ACO or outside the ACO. The beneficiary will be assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by physicians who are ACO professionals with specialty designations as specified in paragraph (c) of this section are greater than the allowed charges for primary care services furnished by physicians with specialty

designations as specified in paragraph (c) of this section—

(i) Who are ACO professionals in any other ACO; or

(ii) Who are unaffiliated with an ACO and are identified by a Medicare-enrolled billing TIN.

(c) ACO professionals considered in the second step of the assignment methodology in paragraph (b)(4) of this section include physicians who have one of the following primary specialty designations:

(1) Cardiology.

(2) Osteopathic manipulative medicine.

(3) Neurology.

(4) Obstetrics/gynecology.

(5) Sports medicine.

(6) Physical medicine and rehabilitation.

(7) Psychiatry.

(8) Geriatric psychiatry.

(9) Pulmonary disease.

(10) Nephrology.

(11) Endocrinology.

(12) Multispecialty clinic or group practice.

(13) Addiction medicine.

(14) Hematology.

(15) Hematology/oncology.

(16) Preventive medicine.

(17) Neuropsychiatry.

(18) Medical oncology.

(19) Gynecology/oncology.

(d) When considering services furnished by ACO professionals in teaching hospitals that have elected under § 415.160 of this subchapter to receive payment on a reasonable cost basis for the direct medical and surgical services of their physicians in the assignment methodology under paragraph (b) of this section, CMS uses an estimated amount based on the amounts payable under the physician fee schedule for similar services in the geographic location of the teaching hospital as a proxy for the amount of the allowed charges for the service.

(e) For performance year 2018 and subsequent performance years, if a system is available to allow a beneficiary to designate a provider or supplier as responsible for coordinating their overall care and for CMS to process the designation electronically, CMS will supplement the claims-based assignment methodology described in this section

with information provided by beneficiaries regarding the provider or supplier they consider responsible for coordinating their overall care. Such designations must be made in the form and manner and by a deadline determined by CMS.

(1) Notwithstanding the assignment methodology under paragraph (b) of this section, beneficiaries who designate an ACO professional participating in an ACO as responsible for coordinating their overall care are prospectively assigned to that ACO, regardless of track, annually at the beginning of each benchmark and performance year based on available data at the time assignment lists are determined for the benchmark and performance year.

(2) Beneficiaries are added to the ACO's list of assigned beneficiaries if all of the following conditions are satisfied:

(i) For performance year 2018:

(A) The beneficiary must have had at least one primary care service during the assignment window as defined under § 425.20 with a physician who is an ACO professional in the ACO who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in paragraph (c) of this section.

(B) The beneficiary meets the eligibility criteria established at § 425.401(a) and must not be excluded by the criteria at § 425.401(b). The exclusion criteria at § 425.401(b) apply for purposes of determining beneficiary eligibility for alignment to ACOs under all tracks based on the beneficiary's designation of an ACO professional as responsible for coordinating their overall care under paragraph (e) of this section.

(C) The beneficiary must have designated an ACO professional who is a primary care physician as defined at § 425.20, a physician with a specialty designation included at paragraph (c) of this section, or a nurse practitioner, physician assistant, or clinical nurse specialist as responsible for coordinating their overall care.

(D) If a beneficiary has designated a provider or supplier outside the ACO who is a primary care physician as defined at § 425.20, a physician with a specialty designation included at para-

graph (c) of this section, or a nurse practitioner, physician assistant, or clinical nurse specialist, as responsible for coordinating their overall care, the beneficiary is not added to the ACO's list of assigned beneficiaries under the assignment methodology in paragraph (b) of this section.

(ii) For performance years starting on January 1, 2019, and subsequent performance years:

(A) The beneficiary meets the eligibility criteria established at § 425.401(a) and must not be excluded by the criteria at § 425.401(b). The exclusion criteria at § 425.401(b) apply for purposes of determining beneficiary eligibility for alignment to an ACO based on the beneficiary's designation of an ACO professional as responsible for coordinating their overall care under paragraph (e) of this section, regardless of the ACO's assignment methodology selection under § 425.400(a)(4)(ii).

(B) The beneficiary must have designated an ACO professional as responsible for coordinating their overall care.

(C) If a beneficiary has designated a provider or supplier outside the ACO as responsible for coordinating their overall care, the beneficiary is not added under the assignment methodology in paragraph (b) of this section to the ACO's list of assigned beneficiaries for a 12-month performance year or the ACO's list of assigned beneficiaries for a 6-month performance year, which is based on the entire CY 2019 as provided in § 425.609.

(D) The beneficiary is not assigned to an entity participating in a model tested or expanded under section 1115A of the Act under which claims-based assignment is based solely on claims for services other than primary care services and for which there has been a determination by the Secretary that waiver of the requirement in section 1899(c)(2)(B) of the Act is necessary solely for purposes of testing the model.

(3) The ACO, ACO participants, ACO providers/suppliers, ACO professionals, and other individuals or entities performing functions and services related to ACO activities are prohibited from providing or offering gifts or other remuneration to Medicare beneficiaries

as inducements for influencing a Medicare beneficiary's decision to designate or not to designate an ACO professional under paragraph (e) of this section. The ACO, ACO participants, ACO providers/suppliers, ACO professionals, and other individuals or entities performing functions and services related to ACO activities must not, directly or indirectly, commit any act or omission, nor adopt any policy that coerces or otherwise influences a Medicare beneficiary's decision to designate or not to designate an ACO professional as responsible for coordinating their overall care under paragraph (e) of this section, including but not limited to the following:

(i) Offering anything of value to the Medicare beneficiary as an inducement to influence the Medicare beneficiary's decision to designate or not to designate an ACO professional as responsible for coordinating their overall care under paragraph (e) of this section. Any items or services provided in violation of paragraph (e)(3) of this section are not considered to have a reasonable connection to the medical care of the beneficiary, as required under § 425.304(b)(1).

(ii) Withholding or threatening to withhold medical services or limiting or threatening to limit access to care.

(f) For performance year 2023 and subsequent performance years, CMS employs the following process to identify services furnished by FQHCs, RHCs, Method II CAHs, and ETA hospitals for purposes of the beneficiary assignment methodology under this section.

(1) Prior to the start of the performance year and periodically during the performance year, CMS will determine the CCNs for all FQHCs, RHCs, Method II CAHs, and ETA hospitals enrolled under the TIN of an ACO participant, including all CCNs with an active enrollment in Medicare and all CCNs with a deactivated enrollment status.

(2) CMS uses the CCNs identified in paragraph (f)(1) of this section in determining assignment for the performance year.

(3) CMS accounts for changes in CCN enrollment status during the performance year as follows:

(i) If a CCN with no prior Medicare claims experience enrolls under the TIN of an ACO participant after the ACO certifies its ACO participant list for a performance year as required under § 425.118(a)(3), CMS will consider services furnished by that CCN in determining beneficiary assignment to the ACO for the applicable performance year for ACOs under preliminary prospective assignment with retrospective reconciliation.

(ii) Services furnished by a CCN with a deactivated enrollment status that is enrolled under an ACO participant at the start of a performance year will be considered in determining beneficiary assignment to the ACO for the applicable performance year or benchmark year.

(iii) If a CCN enrolled under the TIN of an ACO participant at the start of the performance year enrolls under a different TIN during a performance year, CMS will continue to treat services billed by the CCN as services furnished by the ACO participant it was enrolled under at the start of the performance year for purposes of determining beneficiary assignment to the ACO for the applicable performance year.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32841, June 9, 2015; 80 FR 71386, Nov. 16, 2015; 81 FR 80559, Nov. 15, 2016; 83 FR 60093, Nov. 23, 2018; 83 FR 68069, Dec. 31, 2018; 87 FR 70234, Nov. 18, 2022]

#### **§ 425.404 Special assignment conditions for ACOs including FQHCs and RHCs.**

CMS assigns beneficiaries to ACOs based on services furnished in FQHCs or RHCs or both consistent with the general assignment methodology in § 425.402, with special conditions:

(a) For performance years 2012 through 2018—

(1) Such ACOs are required to identify, through an attestation, physicians who directly provide primary care services in each FQHC or RHC that is an ACO participant and/or ACO provider/supplier in the ACO.

(2) Under the assignment methodology in § 425.402, CMS treats a service reported on an FQHC/RHC claim as a primary care service—