

paragraph (a)(2) of this section (as appropriate) to identify trends and patterns suggesting that an ACO has avoided at-risk beneficiaries. The results of these analyses may subsequently require further investigation and follow-up with beneficiaries or the ACO and its ACO participants, ACO providers/suppliers, or other individuals or entities performing functions or services related to the ACO's activities, in order to substantiate cases of beneficiary avoidance.

(2)(i) CMS, at its sole discretion, may take any of the pre-termination actions set forth in § 425.216(a)(1) or immediately terminate, if it determines that an ACO, its ACO participants, any ACO providers/suppliers, or other individuals or entities performing functions or services related to the ACO's activities avoids at-risk beneficiaries.

(ii) If CMS requires the ACO to submit a CAP, the ACO will—

(A) Submit a CAP that addresses actions the ACO will take to ensure that the ACO, ACO participants, ACO providers/suppliers, or other individuals or entities performing functions or services related to the ACO's activities cease avoidance of at-risk beneficiaries.

(B) Not receive any shared savings payments during the time it is under the CAP.

(C) Not be eligible to receive shared savings for the performance year attributable to the time that necessitated the CAP (the time period during which the ACO avoided at risk beneficiaries).

(iii) CMS will re-evaluate the ACO during and after the CAP implementation period to determine if the ACO has continued to avoid at-risk beneficiaries. The ACO will be terminated if CMS determines that the ACO has continued to avoid at-risk beneficiaries during or after the CAP implementation period.

(c) *Monitoring ACO compliance with quality performance standards.* To identify ACOs that are not meeting the quality performance standards, CMS will review an ACO's submission of quality measurement data under § 425.500 or § 425.512. CMS may request additional documentation from an ACO, ACO participants, or ACO pro-

viders/suppliers, as appropriate. If an ACO does not meet quality performance standards or fails to report on one or more quality measures, CMS will take the following actions:

(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* (i) The ACO may be given a warning for the first time it fails to meet the minimum attainment level on at least 70 percent of the measures, as determined under § 425.502, in one or more domains and may be subject to a CAP. CMS may forgo the issuance of the warning letter depending on the nature and severity of the noncompliance and instead subject the ACO to actions set forth at § 425.216 or immediately terminate the ACO's participation agreement under § 425.218.

(ii) The ACO's compliance with the quality performance standards will be re-evaluated the following year. If the ACO continues to fail to meet the quality performance standard in the following year, the agreement will be terminated.

(iii) An ACO will not qualify to share in savings in any year it fails to report accurately, completely, and timely on the quality performance measures.

(2) *For performance years beginning on or after January 1, 2021.* (i) If the ACO fails to meet the quality performance standard, CMS may take one or more of the actions prior to termination specified in § 425.216. Depending on the nature and severity of the noncompliance, CMS may forgo pre-termination actions and may immediately terminate the ACO's participation agreement under § 425.218.

(ii) CMS will terminate an ACO's participation agreement under any of the following circumstances:

(A) The ACO fails to meet the quality performance standard for 2 consecutive performance years within an agreement period.

(B) The ACO fails to meet the quality performance standard for any 3 performance years within an agreement period, regardless of whether the years are in consecutive order.

(C) A renewing ACO or re-entering ACO fails to meet the quality performance standard for the last performance year of the ACO's previous agreement period and this occurrence was either

the second consecutive performance year of failed quality performance or the third nonconsecutive performance year of failed quality performance during the previous agreement period.

(D) A renewing ACO or re-entering ACO fails to meet the quality performance standard for 2 consecutive performance years across 2 agreement periods, specifically the last performance year of the ACO's previous agreement period and the first performance year of the ACO's new agreement period.

(d) *Monitoring ACO financial performance.* (1) For performance years beginning on July 1, 2019 and subsequent performance years, CMS determines whether the Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries for the performance year exceed the ACO's updated benchmark by an amount equal to or exceeding either the ACO's negative MSR under a one-sided model, or the ACO's MLR under a two-sided model.

(2) If the Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries for the performance year exceed the ACO's updated benchmark as specified in paragraph (d)(1) of this section, CMS may take any of the pre-termination actions set forth in § 425.216.

(3) If the Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries for the performance year exceed the ACO's updated benchmark as specified in paragraph (d)(1) of this section for another performance year of the agreement period, CMS may immediately or with advance notice terminate the ACO's participation agreement under § 425.218.

(e) *Monitoring ACO eligibility for advance investment payments.* (1) CMS monitors an ACO that receives advance investment payments pursuant to § 425.630 for changes in its ACO participants that may cause the ACO to no longer meet the standards specified in § 425.630(b)(3) and (4).

(2) If CMS determines that an ACO participating in advance investment payments became experienced with performance-based risk Medicare ACO initiatives during its first or second performance year of its agreement period or that the ACO became a high

revenue ACO during any performance year of its agreement period, CMS—

(i) Will cease payment of advance investment payments no later than the quarter after the ACO became experienced with performance-based risk Medicare ACO initiatives or became a high revenue ACO.

(ii) May take compliance action as specified in §§ 425.216 and 425.218.

(3) If an ACO remains an ACO experienced with performance-based risk Medicare ACO initiatives or a high revenue ACO after a deadline specified by CMS pursuant to compliance action under this section, the ACO must repay all advance investment payments it received. CMS will provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32840, June 9, 2015; 81 FR 80559, Nov. 15, 2016; 83 FR 68069, Dec. 31, 2018; 85 FR 85039, Dec. 28, 2020; 87 FR 70233, Nov. 18, 2022; 88 FR 79544, Nov. 16, 2023]

Subpart E—Assignment of Beneficiaries

§ 425.400 General.

(a)(1) *General.* CMS employs the assignment methodology described in § 425.402 and § 425.404 for purposes of benchmarking, preliminary prospective assignment (including quarterly updates), retrospective reconciliation, and prospective assignment.

(i) A Medicare fee-for-service beneficiary is assigned to an ACO if the—

(A) Beneficiary meets the eligibility criteria under § 425.401(a); and

(B) Beneficiary's utilization of primary care services meets the criteria established under the assignment methodology described in § 425.402 and § 425.404.

(ii) CMS applies a step-wise process based on the beneficiary's utilization of primary care services provided under Title XVIII by a physician who is an ACO professional during each performance year for which shared savings are to be determined and, with respect to ACOs participating in a 6-month performance year during CY 2019, during the entirety of CY 2019 as specified in § 425.609.

(2) *Preliminary prospective assignment with retrospective reconciliation.* (i) Medicare assigns beneficiaries in a preliminary manner at the beginning of a performance year based on most recent data available.

(ii) Assignment will be updated quarterly based on the most recent 12 or 24 months of data, as applicable, under the methodology described in §§ 425.402 and 425.404.

(iii) In determining final assignment for a benchmark or performance year, CMS will exclude any services furnished during the benchmark or performance year that are billed through the TIN of an ACO participant that is an ACO participant in more than one ACO.

(3) *Prospective assignment.* (i) Medicare fee-for-service beneficiaries are prospectively assigned to an ACO at the beginning of each benchmark or performance year based on the beneficiary's use of primary care services in the most recent 12 or 24 months, as applicable, for which data are available, using the assignment methodology described in §§ 425.402 and 425.404.

(ii) Beneficiaries that are prospectively assigned to an ACO under paragraph (a)(3)(i) of this section will remain assigned to the ACO at the end of the benchmark or performance year unless they meet any of the exclusion criteria under § 425.401(b).

(4) *Assignment methodology applied to ACO.* (i) For agreement periods beginning before July 1, 2019, the applicable assignment methodology is determined based on track as specified in § 425.600(a).

(A) Preliminary prospective assignment with retrospective reconciliation as described in paragraph (a)(2) of this section applies to Track 1 and Track 2 ACOs.

(B) Prospective assignment as described in paragraph (a)(3) of this section applies to Track 3 ACOs.

(ii) For agreement periods beginning on July 1, 2019 and in subsequent years, an ACO may select the assignment methodology that CMS employs for assignment of beneficiaries under this subpart.

(A) An ACO may select either of the following:

(1) Preliminary prospective assignment with retrospective reconciliation, as described in paragraph (a)(2) of this section.

(2) Prospective assignment, as described in paragraph (a)(3) of this section.

(B) This selection is made prior to the start of each agreement period, and may be modified prior to the start of each performance year as specified in § 425.226.

(b) Beneficiary assignment to an ACO is for purposes of determining the population of Medicare fee-for-service beneficiaries for whose care the ACO is accountable under subpart F of this part, and for determining whether an ACO has achieved savings under subpart G of this part, and in no way diminishes or restricts the rights of beneficiaries assigned to an ACO to exercise free choice in determining where to receive health care services.

(c) Primary care services for purposes of assigning beneficiaries are identified by selected HCPSC/CPT codes, or revenue center codes.

(1) Primary care service codes are as follows:

(i) For performance years 2012 through 2015:

(A) CPT codes:

(1) 99201 through 99215.

(2) 99304 through 99340.

(3) 99341 through 99350.

(B) HCPSC codes G0402 (the code for the Welcome to Medicare visit) and G0438 and G0439 (codes for the annual wellness visits).

(C) Revenue center codes 0521, 0522, 0524, and 0525 submitted by FQHCs (for services furnished prior to January 1, 2011), or by RHCs.

(ii) For performance year 2016 as follows:

(A) CPT codes:

(1) 99201 through 99215.

(2) 99304 through 99340.

(3) 99341 through 99350.

(4) 99495, 99496, and 99490.

(B) HCPSC codes:

(1) G0402 (the code for the Welcome to Medicare visit) and

(2) G0438 and G0439 (codes for the annual wellness visits).

(3) G0463 for services furnished in ETA hospitals.

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(C) Revenue center codes 0521, 0522, 0524, and 0525 submitted by FQHCs (for services furnished prior to January 1, 2011), or by RHCs.

(iii) For performance years 2017 and 2018 as follows:

(A) CPT codes:

(1) 99201 through 99215.

(2) 99304 through 99318 (excluding claims including the POS 31 modifier).

(3) 99319 through 99340.

(4) 99341 through 99350.

(5) 99495, 99496, and 99490.

(B) HCPCS Codes:

(1) G0402 (the code for the Welcome to Medicare visit) and

(2) G0438 and G0439 (codes for the annual wellness visits).

(3) G0463 for services furnished in ETA hospitals.

(C) Revenue center codes 0521, 0522, 0524, and 0525 submitted by FQHCs (for services furnished prior to January 1, 2011), or by RHCs.

(iv) For performance years (or a performance period) during 2019, and performance year 2020 as follows:

(A) CPT codes:

(1) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(2) 99304 through 99318 (codes for professional services furnished in a nursing facility; services identified by these codes furnished in a SNF are excluded).

(3) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(4) 99341 through 99350 (codes for evaluation and management services furnished in a patients' home for claims identified by place of service modifier 12).

(5) 99487, 99489 and 99490 (codes for chronic care management).

(6) 99495 and 99496 (codes for transitional care management services).

(7) 99497 and 99498 (codes for advance care planning).

(8) 96160 and 96161 (codes for administration of health risk assessment).

(9) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)).

(10) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(B) HCPCS codes:

(1) G0402 (the code for the Welcome to Medicare visit) and

(2) G0438 and G0439 (codes for the annual wellness visits).

(3) G0463 for services furnished in ETA hospitals.

(4) G0506 (code for chronic care management).

(5) G0444 (codes for annual depression screening service).

(6) G0442 (code for alcohol misuse screening service).

(7) G0443 (code for alcohol misuse counseling service).

(v) For the performance year starting on January 1, 2021:

(A) CPT codes:

(1) 96160 and 96161 (codes for administration of health risk assessment).

(2) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(3) 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a SNF).

(4) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(5) 99341 through 99350 (codes for evaluation and management services furnished in a patient's home for claims identified by place of service modifier 12).

(6) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)(v)).

(7) 99421, 99422, and 99423 (codes for online digital evaluation and management).

(8) 99439 (code for non-complex chronic care management).

(9) 99483 (code for assessment of and care planning for patients with cognitive impairment).

(10) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

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(11) 99487, 99489, 99490 and 99491 (codes for chronic care management).

(12) 99495 and 99496 (codes for transitional care management services).

(13) 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

(B) HCPCS codes:

(1) G0402 (code for the Welcome to Medicare visit).

(2) G0438 and G0439 (codes for the annual wellness visits).

(3) G0442 (code for alcohol misuse screening service).

(4) G0443 (code for alcohol misuse counseling service).

(5) G0444 (code for annual depression screening service).

(6) G0463 (code for services furnished in ETA hospitals).

(7) G0506 (code for chronic care management).

(8) G2010 (code for the remote evaluation of patient video/images).

(9) G2012 (code for virtual check-in).

(10) G2058 (code for non-complex chronic care management).

(11) G2064 and G2065 (codes for principal care management services).

(12) G2214 (code for psychiatric collaborative care model).

(vi) For the performance year starting on January 1, 2022 as follows:

(A) CPT codes:

(1) 96160 and 96161 (codes for administration of health risk assessment).

(2) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(3) 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a SNF).

(4) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(5) 99341 through 99350 (codes for evaluation and management services furnished in a patient's home for claims identified by place of service modifier 12).

(6) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary

procedure; when the base code is also a primary care service code under this paragraph (c)(1)(vi)).

(7) 99421, 99422, and 99423 (codes for online digital evaluation and management).

(8) 99424, 99425, 99426, and 99427 (codes for principal care management services).

(9) 99437, 99487, 99489, 99490 and 99491 (codes for chronic care management).

(10) 99439 (code for non-complex chronic care management).

(11) 99483 (code for assessment of and care planning for patients with cognitive impairment).

(12) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(13) 99495 and 99496 (codes for transitional care management services).

(14) 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

(B) HCPCS codes:

(1) G0402 (code for the Welcome to Medicare visit).

(2) G0438 and G0439 (codes for the annual wellness visits).

(3) G0442 (code for alcohol misuse screening service).

(4) G0443 (code for alcohol misuse counseling service).

(5) G0444 (code for annual depression screening service).

(6) G0463 (code for services furnished in ETA hospitals).

(7) G0506 (code for chronic care management).

(8) G2010 (code for the remote evaluation of patient video/images).

(9) G2012 and G2252 (codes for virtual check-in).

(10) G2058 (code for non-complex chronic care management).

(11) G2064 and G2065 (codes for principal care management services).

(12) G2212 (code for prolonged office or other outpatient visit for the evaluation and management of a patient).

(13) G2214 (code for psychiatric collaborative care model).

(C) Primary care service codes include any CPT code identified by CMS that directly replaces a CPT code specified in paragraph (c)(1)(vi)(A) of this section or a HCPCS code specified in paragraph (c)(1)(vi)(B) of this section,

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when the assignment window (as defined in § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

(vii) For the performance year starting on January 1, 2023 as follows:

(A) CPT codes:

(1) 96160 and 96161 (codes for administration of health risk assessment).

(2) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(3) 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a SNF).

(4) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(5) 99341 through 99350 (codes for evaluation and management services furnished in a patient's home).

(6) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)(vii)).

(7) 99421, 99422, and 99423 (codes for online digital evaluation and management).

(8) 99424, 99425, 99426, and 99427 (codes for principal care management services).

(9) 99437, 99487, 99489, 99490 and 99491 (codes for chronic care management).

(10) 99439 (code for non-complex chronic care management).

(11) 99483 (code for assessment of and care planning for patients with cognitive impairment).

(12) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(13) 99495 and 99496 (codes for transitional care management services).

(14) 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

(B) HCPCS codes:

(1) G0402 (code for the Welcome to Medicare visit).

(2) G0438 and G0439 (codes for the annual wellness visits).

(3) G0442 (code for alcohol misuse screening service).

(4) G0443 (code for alcohol misuse counseling service).

(5) G0444 (code for annual depression screening service).

(6) G0463 (code for services furnished in ETA hospitals).

(7) G0506 (code for chronic care management).

(8) G2010 (code for the remote evaluation of patient video/images).

(9) G2012 and G2252 (codes for virtual check-in).

(10) G2058 (code for non-complex chronic care management).

(11) G2064 and G2065 (codes for principal care management services).

(12) G0317, G0318, and G2212 (codes for prolonged office or other outpatient visit for the evaluation and management of a patient).

(13) G2214 (code for psychiatric collaborative care model).

(14) G3002 and G3003 (codes for chronic pain management).

(C) Primary care service codes include any CPT code identified by CMS that directly replaces a CPT code specified in paragraph (c)(1)(vii)(A) of this section or a HCPCS code specified in paragraph (c)(1)(vii)(B) of this section, when the assignment window (as defined in § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

(viii) For the performance year starting on January 1, 2024, and subsequent performance years as follows:

(A) CPT codes:

(1) 96160 and 96161 (codes for administration of health risk assessment).

(2) 96202 and 96203 (codes for caregiver behavior management training).

(3) 97550, 97551, and 97552 (codes for caregiver training services).

(4) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(5) 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC

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claim identified by these codes are excluded when furnished in a SNF).

(6) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(7) 99341 through 99350 (codes for evaluation and management services furnished in a patient's home).

(8) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)(viii)).

(9) 99406 and 99407 (codes for smoking and tobacco-use cessation counseling services).

(10) 99421, 99422, and 99423 (codes for online digital evaluation and management).

(11) 99424, 99425, 99426, and 99427 (codes for principal care management services).

(12) 99437, 99487, 99489, 99490 and 99491 (codes for chronic care management).

(13) 99439 (code for non-complex chronic care management).

(14) 99483 (code for assessment of and care planning for patients with cognitive impairment).

(15) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(16) 99495 and 99496 (codes for transitional care management services).

(17) 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

(B) HCPCS codes:

(1) G0019 and G0022 (codes for community health integration services).

(2) G0023 and G0024 (codes for principal illness navigation services).

(3) G0101 (code for cervical or vaginal cancer screening).

(4) G0136 (code for social determinants of health risk assessment services).

(5) G0317, G0318, and G2212 (codes for prolonged office or other outpatient visit for the evaluation and management of a patient).

(6) G0402 (code for the Welcome to Medicare visit).

(7) G0438 and G0439 (codes for the annual wellness visits).

(8) G0442 (code for alcohol misuse screening service).

(9) G0443 (code for alcohol misuse counseling service).

(10) G0444 (code for annual depression screening service).

(11) G0463 (code for services furnished in ETA hospitals).

(12) G0506 (code for chronic care management).

(13) G2010 (code for the remote evaluation of patient video/images).

(14) G2012 and G2252 (codes for virtual check-in).

(15) G2058 (code for non-complex chronic care management).

(16) G2064 and G2065 (codes for principal care management services).

(17) G2086, G2087, and G2088 (codes for office-based opioid use disorder services).

(18) G2211 (code for visit complexity inherent to evaluation and management services add-on).

(19) G2214 (code for psychiatric collaborative care model).

(20) G3002 and G3003 (codes for chronic pain management).

(C) Primary care service codes include any CPT code identified by CMS that directly replaces a CPT code specified in paragraph (c)(1)(viii)(A) of this section or a HCPCS code specified in paragraph (c)(1)(viii)(B) of this section, when the assignment window (as defined in § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

(2)(i) Except as otherwise specified in paragraph (c)(2)(i)(A)(2) of this section, when the assignment window or applicable expanded window for assignment (as defined in § 425.20) for a benchmark or performance year includes any month(s) during the COVID-19 Public Health Emergency defined in § 400.200 of this chapter, in determining beneficiary assignment, we use the primary care service codes identified in paragraph (c)(1) of this section, and additional primary care service codes as follows:

(A) CPT codes:

(1) 99421, 99422, and 99423 (codes for online digital evaluation and management services).