Title 42 —Public Health

Chapter IV —Centers for Medicare & Medicaid Services, Department of Health and Human Services

Subchapter H —Health Care Infrastructure and Model Programs

PART 512—STANDARD PROVISIONS FOR MANDATORY INNOVATION CENTER MODELS AND SPECIFIC PROVISIONS FOR CERTAIN MODELS

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

Source: 85 FR 61362, Sept. 29, 2020, unless otherwise noted.

Subpart A—Standard Provisions for Mandatory Innovation Center Models

§ 512.100 Basis and scope.

(a) ***Basis.*** This subpart implements standard provisions for certain Innovation Center models, as that term is defined in this subpart.

(b) ***Scope.***

(1) The regulations in this subpart apply to the Radiation Oncology Model implemented under subpart B, the End-Stage Renal Disease (ESRD) Treatment Choices Model implemented under subpart C, and each Innovation Center model for which participation by Model participants is mandatory that begins its first performance period on or after January 1, 2025.

(2) This subpart sets forth the following:

(i) Basis and scope.

(ii) Definitions.

(iii) Beneficiary protections.

(iv) Cooperation in model evaluation and monitoring.

(v) Audits and record retention.

(vi) Rights in data and intellectual property.

(vii) Monitoring and compliance.

(viii) Remedial action.

(ix) Innovation Center model termination by CMS.

(x) Limitations on review.

(xi) Miscellaneous provisions on bankruptcy and other notifications.

(xii) Reconsideration review processes.

(3) Except as specifically noted in this subpart, these regulations do not affect the applicability of other provisions affecting providers and suppliers under Medicare FFS, including provisions regarding payment, coverage, or program integrity.

[89 FR 96444, Dec. 4, 2024]

§ 512.110 Definitions.

For purposes of this part, the following terms are defined as follows unless otherwise stated:

Beneficiary means an individual who is enrolled in Medicare FFS.

Change in control means any of the following:

(1) The acquisition by any “person” (as this term is used in sections 13(d) and 14(d) of the Securities Exchange Act of 1934) of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Securities Exchange Act of 1934), directly or indirectly, of voting securities of the model participant representing more than 50 percent of the model participant's outstanding voting securities or rights to acquire such securities.

(2) The acquisition of the model participant by any individual or entity.

(3) The sale, lease, exchange or other transfer (in one transaction or a series of transactions) of all or substantially all of the assets of the model participant.

(4) The approval and completion of a plan of liquidation of the model participant, or an agreement for the sale or liquidation of the model participant.

Covered services means the scope of health care benefits described in sections 1812 and 1832 of the Act for which payment is available under Part A or Part B of Title XVIII of the Act.

Days means calendar days.

Descriptive model materials and activities means general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, web pages, mailings, social media, or other materials or activities distributed or conducted by or on behalf of the model participant or its downstream participants when used to educate, notify, or contact beneficiaries regarding the Innovation Center model. The following communications are not descriptive model materials and activities: Communications that do not directly or indirectly reference the Innovation Center model (for example, information about care coordination generally); information on specific medical conditions; referrals for health care items and services; and any other materials that are excepted from the definition of “marketing” as that term is defined at 45 CFR 164.501.

Downstream participant means an individual or entity that has entered into a written arrangement with a model participant under which the downstream participant engages in one or more Innovation Center model activities.

Governing documentation means the applicable Federal regulations, and the model-specific participation agreement, cooperative agreement, and any addendum to an existing contract with CMS, that collectively specify the terms of the Innovation Center model.

Innovation Center model means an innovative payment and service delivery model tested under the authority of section 1115A(b) of the Act, including a model expansion under section 1115A(c) of the Act.

Innovation Center model activities mean any activities affecting the care of model beneficiaries related to the test of the Innovation Center model.

Medically necessary means reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body member.

Model beneficiary means a beneficiary attributed to a model participant or otherwise included in an Innovation Center model.

Model participant means an individual or entity that is identified as a participant in the Innovation Center model.

Model-specific payment means a payment made by CMS only to model participants, or a payment adjustment made only to payments made to model participants, under the terms of the Innovation Center model that is not applicable to any other providers or suppliers.

Performance period means the period of time during which an Innovation Center model is tested and model participants are held accountable for cost and quality of care; the performance period for each Innovation Center model is specified in the governing documentation.

Provider means a “provider of services” as defined under section 1861(u) of the Act and codified in the definition of “provider” at § 400.202 of this chapter.

Standard provisions for Innovation Center models mean the provisions codified in 42 CFR part 512 subpart A.

Supplier means a supplier as defined in section 1861(d) of the Act and codified at § 400.202 of this chapter.

U.S. Territories means American Samoa, the Federated States of Micronesia, Guam, the Marshall Islands, and the Commonwealth of the Northern Mariana Islands, Palau, Puerto Rico, U.S. Minor Outlying Islands, and the U.S. Virgin Islands.

[85 FR 61362, Sept. 29, 2020, as amended at 89 FR 96444, Dec. 4, 2024]

§ 512.120 Beneficiary protections.

(a) ***Beneficiary freedom of choice.***

(1) The model participant and its downstream model participants must not restrict beneficiaries' ability to choose to receive care from any provider or supplier.

(2) The model participant and its downstream model participants must not commit any act or omission, nor adopt any policy that inhibits beneficiaries from exercising their freedom to choose to receive care from any provider or supplier or from any health care provider who has opted out of Medicare. The model participant and its downstream model participants may communicate to model beneficiaries the benefits of receiving care with the model participant, if otherwise consistent with the requirements of this part and applicable law.

(b) ***Availability of services.***

(1) The model participant and its downstream participants must continue to make medically necessary covered services available to beneficiaries to the extent required by applicable law. Model beneficiaries and their assignees retain their rights to appeal claims in accordance with part 405, subpart I of this chapter.

(2) The model participant and its downstream participants must not take any action to select or avoid treating certain Medicare beneficiaries based on their income levels or based on factors that would render the beneficiary an “at-risk beneficiary” as defined at § 425.20 of this chapter.

(3) The model participant and its downstream participants must not take any action to selectively target or engage beneficiaries who are relatively healthy or otherwise expected to improve the model participant's or downstream participant's financial or quality performance, a practice commonly referred to as “cherry-picking.”

(c) ***Descriptive model materials and activities.***

(1) The model participant and its downstream participants must not use or distribute descriptive model materials and activities that are materially inaccurate or misleading.

(2) The model participant and its downstream participants must include the following statement on all descriptive model materials and activities: "The statements contained in this document are solely those of the authors and do not necessarily reflect the views or policies of the Centers for Medicare & Medicaid Services (CMS). The authors assume responsibility for the accuracy and completeness of the information contained in this document."

(3) The model participant and its downstream participants must retain copies of all written and electronic descriptive model materials and activities and appropriate records for all other descriptive model materials and activities in a manner consistent with § 512.135(c).

(4) CMS reserves the right to review, or have a designee review, descriptive model materials and activities to determine whether or not the content is materially inaccurate or misleading. This review takes place at a time and in a manner specified by CMS once the descriptive model materials and activities are in use by the model participant.

§ 512.130 Cooperation in model evaluation and monitoring.

The model participant and its downstream participants must comply with the requirements of § 403.1110(b) of this chapter and must otherwise cooperate with CMS' model evaluation and monitoring activities as may be necessary to enable CMS to evaluate the Innovation Center model in accordance with section 1115A(b)(4) of the Act and to conduct monitoring activities under § 512.150, including producing such data as may be required by CMS to evaluate or monitor the Innovation Center model, which may include protected health information as defined in 45 CFR 160.103 and other individually-identifiable data.

§ 512.135 Audits and record retention.

(a) ***Right to audit.*** The Federal government, including CMS, HHS, and the Comptroller General, or their designees, has the right to audit, inspect, investigate, and evaluate any documents and other evidence regarding implementation of an Innovation Center model.

(b) ***Access to records.*** The model participant and its downstream participants must maintain and give the Federal government, including CMS, HHS, and the Comptroller General, or their designees, access to all such documents and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the implementation of the Innovation Center model, including without limitation, documents and other evidence regarding all of the following:

(1) The model participant's and its downstream participants' compliance with the terms of the Innovation Center model, including this subpart.

(2) The accuracy of model-specific payments made under the Innovation Center model.

(3) The model participant's payment of amounts owed to CMS under the Innovation Center model.

(4) Quality measure information and the quality of services performed under the terms of the Innovation Center model, including this subpart.

(5) Utilization of items and services furnished under the Innovation Center model.

(6) The ability of the model participant to bear the risk of potential losses and to repay any losses to CMS, as applicable.

(7) Patient safety.

(8) Other program integrity issues.

(c) *Record retention.*

(1) The model participant and its downstream participants must maintain the documents and other evidence described in paragraph (b) of this section and other evidence for a period of six years from the last payment determination for the model participant under the Innovation Center model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the model participant at least 30 days before the normal disposition date; or

(ii) There has been a termination, dispute, or allegation of fraud or similar fault against the model participant or its downstream participants, in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

(2) If CMS notifies the model participant of the special need to retain records in accordance with paragraph (c)(1)(i) of this section or there has been a termination, dispute, or allegation of fraud or similar fault against the model participant or its downstream participants described in paragraph (c)(1)(ii) of this section, the model participant must notify its downstream participants of this need to retain records for the additional period specified by CMS.

§ 512.140 Rights in data and intellectual property.

(a) CMS may—

(1) Use any data obtained under §§ 512.130, 512.135, and 512.150 to evaluate and monitor the Innovation Center model; and

(2) Disseminate quantitative and qualitative results and successful care management techniques, including factors associated with performance, to other providers and suppliers and to the public. Data disseminated may include patient—

(i) De-identified results of patient experience of care and quality of life surveys, and

(ii) De-identified measure results calculated based upon claims, medical records, and other data sources.

(b) Notwithstanding any other provision of this part, for all data that CMS confirms to be proprietary trade secret information and technology of the model participant or its downstream participants, CMS or its designee(s) will not release this data without the express written consent of the model participant or its downstream participant, unless such release is required by law.

(c) If the model participant or its downstream participant wishes to protect any proprietary or confidential information that it submits to CMS or its designee, the model participant or its downstream participant must label or otherwise identify the information as proprietary or confidential. Such assertions are subject to review and confirmation by CMS prior to CMS' acting upon such assertions.

§ 512.150 Monitoring and compliance.

(a) ***Compliance with laws.*** The model participant and each of its downstream participants must comply with all applicable laws and regulations.

(b) ***CMS monitoring and compliance activities.***

(1) CMS may conduct monitoring activities to ensure compliance by the model participant and each of its downstream participants with the terms of the Innovation Center model including this subpart; to understand model participants' use of model-specific payments; and to promote the safety of beneficiaries and the integrity of the Innovation Center model. Such monitoring activities may include, without limitation, all of the following:

(i) Documentation requests sent to the model participant and its downstream participants, including surveys and questionnaires.

(ii) Audits of claims data, quality measures, medical records, and other data from the model participant and its downstream participants.

(iii) Interviews with members of the staff and leadership of the model participant and its downstream participants.

(iv) Interviews with beneficiaries and their caregivers.

(v) Site visits to the model participant and its downstream participants, performed in a manner consistent with paragraph (c) of this section.

(vi) Monitoring quality outcomes and clinical data, if applicable.

(vii) Tracking patient complaints and appeals.

(2) In conducting monitoring and oversight activities, CMS or its designees may use any relevant data or information including without limitation all Medicare claims submitted for items or services furnished to model beneficiaries.

(c) ***Site visits.***

(1) In a manner consistent with § 512.130, the model participant and its downstream participants must cooperate in periodic site visits performed by CMS or its designees in order to facilitate the evaluation of the Innovation Center model and the monitoring of the model participant's compliance with the terms of the Innovation Center model, including this subpart.

(2) CMS or its designee provides, to the extent practicable, the model participant or downstream participant with no less than 15 days advance notice of any site visit. CMS—

(i) Will attempt, to the extent practicable, to accommodate a request for particular dates in scheduling site visits.

(ii) Will not accept a date request from a model participant or downstream participant that is more than 60 days after the date of the CMS initial site visit notice.

(3) The model participant and its downstream participants must ensure that personnel with the appropriate responsibilities and knowledge associated with the purpose of the site visit are available during all site visits.

(4) Additionally, CMS may perform unannounced site visits at the office of the model participant and any of its downstream participants at any time to investigate concerns about the health or safety of beneficiaries or other patients or other program integrity issues.

(5) Nothing in this part shall be construed to limit or otherwise prevent CMS from performing site visits permitted or required by applicable law.

(d) ***Reopening of payment determinations.***

(1) CMS may reopen a model-specific payment determination on its own motion or at the request of a model participant, within 4 years from the date of the determination, for good cause (as defined at § 405.986 of this chapter).

(2) CMS may reopen a model-specific payment determination at any time if there exists reliable evidence (as defined in § 405.902 of this chapter) that the determination was procured by fraud or similar fault (as defined in § 405.902 of this chapter).

(3) CMS's decision regarding whether to reopen a model-specific payment determination is binding and not subject to appeal.

(e) ***OIG authority.*** Nothing contained in the terms of the Innovation Center Model or this part limits or restricts the authority of the HHS Office of Inspector General or any other Federal government authority, including its authority to audit, evaluate, investigate, or inspect the model participant or its downstream participants for violations of any Federal statutes, rules, or regulations.

§ 512.160 Remedial action.

(a) ***Grounds for remedial action.*** CMS may take one or more remedial actions described in paragraph (b) of this section if CMS determines that the model participant or a downstream participant:

(1) Has failed to comply with any of the terms of the Innovation Center Model, including this subpart.

(2) Has failed to comply with any applicable Medicare program requirement, rule, or regulation.

(3) Has taken any action that threatens the health or safety of a beneficiary or other patient.

(4) Has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the Innovation Center model.

(5) Has undergone a change in control that presents a program integrity risk.

(6) Is subject to any sanctions of an accrediting organization or a Federal, State, or local government agency.

(7) Is subject to investigation or action by HHS (including the HHS Office of Inspector General and CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including being subject to the filing of a complaint or filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the Federal government has intervened, or similar action.

(8) Has failed to demonstrate improved performance following any remedial action imposed under this section.

(9) For the ETC Model only, has misused or disclosed the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the applicable data sharing agreement.

(b) ***Remedial actions.*** If CMS determines that one or more grounds for remedial action described in paragraph (a) of this section has taken place, CMS may take one or more of the following remedial actions:

(1) Notify the model participant and, if appropriate, require the model participant to notify its downstream participants of the violation.

(2) Require the model participant to provide additional information to CMS or its designees.

(3) Subject the model participant to additional monitoring, auditing, or both.

(4) Prohibit the model participant from distributing model-specific payments, as applicable.

(5) Require the model participant to terminate, immediately or by a deadline specified by CMS, its agreement with a downstream participant with respect to the Innovation Center model.

(6) In the ETC Model only:

(i) Terminate the ETC Participant from the ETC Model.

(ii) Suspend or terminate the ability of the ETC Participant, pursuant to § 512.397(c), to reduce or waive the coinsurance for kidney disease patient education services.

(7) Require the model participant to submit a corrective action plan in a form and manner and by a deadline specified by CMS.

(8) Discontinue the provision of data sharing and reports to the model participant.

(9) Recoup model-specific payments.

(10) Reduce or eliminate a model-specific payment otherwise owed to the model participant.

(11) Such other action as may be permitted under the terms of this part.

[85 FR 61362, Sept. 29, 2020, as amended at 86 FR 62020, Nov. 8, 2021]

§ 512.165 Innovation center model termination by CMS.

(a) CMS may terminate an Innovation Center model for reasons including, but not limited to, the following:

(1) CMS determines that it no longer has the funds to support the Innovation Center model.

(2) CMS terminates the Innovation Center model in accordance with section 1115A(b)(3)(B) of the Act.

(b) If CMS terminates an Innovation Center model, CMS provides written notice to the model participant specifying the grounds for model termination and the effective date of such termination.

§ 512.170 Limitations on review.

There is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for all of the following:

(a) The selection of models for testing or expansion under section 1115A of the Act.

(b) The selection of organizations, sites, or participants, including model participants, to test the Innovation Center models selected, including a decision by CMS to remove a model participant or to require a model participant to remove a downstream participant from the Innovation Center model.

(c) The elements, parameters, scope, and duration of such Innovation Center models for testing or dissemination, including without limitation the following:

(1) The selection of quality performance standards for the Innovation Center model by CMS.

(2) The methodology used by CMS to assess the quality of care furnished by the model participant.

(3) The methodology used by CMS to attribute model beneficiaries to the model participant, if applicable.

(d) Determinations regarding budget neutrality under section 1115A(b)(3) of the Act.

(e) The termination or modification of the design and implementation of an Innovation Center model under section 1115A(b)(3)(B) of the Act.

(f) Determinations about expansion of the duration and scope of an Innovation Center model under section 1115A(c) of the Act, including the determination that an Innovation Center model is not expected to meet criteria described in paragraph (a) or (b) of such section.

§ 512.180 Miscellaneous provisions on bankruptcy and other notifications.

(a) ***Notice of bankruptcy.*** If the model participant has filed a bankruptcy petition, whether voluntary or involuntary, the model participant must provide written notice of the bankruptcy to CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed, unless final payment has been made by either CMS or the model participant under the terms of each model tested under section 1115A of the Act in which the model participant is participating or has participated and all administrative or judicial review proceedings relating to any payments under such models have been fully and finally resolved. The notice of bankruptcy must be sent by certified mail no later than 5 days after the petition has been filed and must contain a copy of the filed bankruptcy petition (including its docket number), and a list of all models tested under section 1115A of the Act in which the model participant is participating or has participated. This list need not identify a model tested under section 1115A of the Act in which the model participant participated if final payment has been made under the terms of the model and all administrative or judicial review proceedings regarding model-specific payments between the model participant and CMS have been fully and finally resolved with respect to that model. The notice to CMS must be addressed to the CMS Office of Financial Management at 7500 Security Boulevard, Mailstop C3-01-24, Baltimore, MD 21244 or such other address as may be specified on the CMS website for purposes of receiving such notices.

(b) ***Notice of legal name change.*** A model participant must furnish written notice to CMS at least 30 days after any change in its legal name becomes effective. The notice of legal name change must be in a form and manner specified by CMS and must include a copy of the legal document effecting the name change, which must be authenticated by the appropriate State official.

(c) ***Notice of change in control.***

(1) A model participant must furnish written notice to CMS in a form and manner specified by CMS at least 90 days before any change in control becomes effective.

(2)

(i) If CMS determines, in accordance with § 512.160(a)(5), that a model participant's change in control would present a program integrity risk, CMS may take remedial action against the model participant under § 512.160(b).

(ii) CMS may also require immediate reconciliation and payment of all monies owed to CMS by a model participant that is subject to a change in control.

§ 512.190 Reconsideration review process.

(a) ***Applicability of this section.*** Section 512.190 is only applicable to the following:

(1) Innovation Center models that have waived section 1869 of the Act, or where section 1869 of the Act is not applicable for model participants.

(2) Model participants, unless the governing documentation for the Innovation Center model states otherwise.

(b) ***Right to reconsideration.*** The model participant may request reconsideration of a determination made by CMS in accordance with an Innovation Center model's governing documentation only if such reconsideration is not precluded by section 1115A(d)(2) of the Act, this subpart, or the governing documentation for the Innovation Center model for which CMS made the initial determination.

(1) A request for reconsideration by the model participant must satisfy all of the following criteria:

(i) Must be submitted to a designee of CMS (reconsideration official) who—

(A) Is authorized to receive such requests; and

(B) Did not participate in the determination that is the subject of the reconsideration request, or, if applicable, the timely error notice review process.

(ii)

(A) Must include a copy of the initial determination issued by CMS; and

(B) Must contain a detailed, written explanation of the basis for the dispute, including supporting documentation.

(iii) Must be made within 30 days of the date of the initial determination for which reconsideration is being requested via email to an address as specified by CMS in the governing documentation for the Innovation Center model for which CMS made the initial determination.

(2) Requests that do not meet the requirements of paragraph (b)(1) of this section are denied.

(3) Within 10 business days of receiving a request for reconsideration, the reconsideration official sends CMS and the model participant a written acknowledgement of receipt of the reconsideration request. This acknowledgement sets forth all of the following:

(i) The review procedures.

(ii) A schedule that permits each party to submit position papers and documentation in support of the party's position for consideration by the reconsideration official.

(4) If the request is regarding a model-specific payment and the governing documentation specifies an initial timely error notice process, the model participant must satisfy the timely error notice requirements specified in the governing documentation before submitting a reconsideration request under paragraph (b) of this section. In the event that the model participant fails to timely submit an error notice with respect to a particular model-specific payment, the reconsideration review process would not be available to the model participant with regard to that model-specific payment.

(c) ***Standards for reconsideration.***

(1) The parties must continue to fulfill all responsibilities and obligations under the governing documentation during the course of any dispute arising under the governing documentation.

(2) The reconsideration consists of a review of documentation that is submitted timely and in accordance with the standards specified by the reconsideration official and are enumerated in paragraph (b)(3) of this section.

(3) The burden of proof is on the model participant to demonstrate to the reconsideration official with clear and convincing evidence that the determination is inconsistent with the terms of the governing documentation.

(d) ***Reconsideration determination.***

(1) The reconsideration determination is based solely upon both of the following:

(i) Position papers and supporting documentation that meet both of the following:

(A) Submitted timely to the reconsideration official in accordance with the schedule specified in paragraph (b)(3)(ii) of this section.

(B) The standards for submission under paragraph (b)(1) of this section.

(ii) Documents and data that were timely submitted to CMS in the required format before CMS made the determination that is the subject of the reconsideration request.

(2)

(i) The reconsideration official issues the reconsideration determination to CMS and to the model participant in writing.

(ii) Absent unusual circumstances, in which case the reconsideration official reserves the right to an extension upon written notice to the model participant, the reconsideration determination is issued within 60 days of receipt of timely filed position papers and supporting documentation in accordance with the schedule specified in paragraph (b)(3)(ii) of this section.

(3) The reconsideration determination is final and binding 30 days after its issuance, unless the model participant or CMS timely requests review of the reconsideration determination in accordance with paragraphs (e)(1) and (2) of this section.

(e) ***CMS Administrator review.*** The model participant or CMS may request that the CMS Administrator review the reconsideration determination. The request must meet both of the following:

(1) Be made via email within 30 days of the date of the reconsideration determination to the address specified by CMS.

(2) Include a copy of the reconsideration determination and a detailed written explanation of why the model participant or CMS disagrees with the reconsideration determination.

(3) The CMS Administrator promptly sends the parties a written acknowledgement of receipt of the request for review.

(4) The CMS Administrator sends the parties notice of the following:

(i) Whether the request for review is granted or denied.

(ii) If the request for review is granted, the review procedures and a schedule that permits each party to submit a brief in support of the party's position for consideration by the CMS Administrator.

(4) If the request for review is denied, the reconsideration determination is final and binding as of the date the request for review is denied.

(5) If the request for review is granted all of the following occur:

(i) The record for review consists solely of—

(A) Timely submitted briefs and the evidence contained in the record of the proceedings before the reconsideration official; and

(B) Evidence as set forth in the documents and data described in paragraph (d)(1)(ii) of this section.

(ii) The CMS Administrator reviews the record and issues to CMS and to the model participant a written determination.

(iii) The written determination of the CMS Administrator is final and binding as of the date the written determination is sent.

[89 FR 96444, Dec. 4, 2024]

Editorial Note: At 89 FR 96444, Dec. 4, 2024, § 512.190 was added with two paragraph (e)(4)s.

Subpart B—Radiation Oncology Model

GENERAL

§ 512.200 Basis and scope of subpart.

(a) ***Basis.*** This subpart implements the test of the Radiation Oncology (RO) Model under section 1115A(b) of the Act. Except as specifically noted in this subpart, the regulations under this subpart do not affect the applicability of other regulations affecting providers and suppliers under Medicare FFS, including the applicability of regulations regarding payment, coverage, and program integrity.

(b) ***Scope.*** This subpart sets forth the following:

(1) RO Model participation.

(2) Episodes being tested under the RO Model.

(3) Methodology for pricing.

(4) Billing and payment under the RO Model.

(5) Data reporting requirements.

(6) Medicare program waivers.

(7) Payment reconciliation and review processes.

(c) RO participants are subject to the general provisions for Innovation Center models specified in subpart A of this part 512 and in subpart K of part 403 of this chapter.

§ 512.205 Definitions.

For purposes of this subpart, the following definitions apply:

Aggregate quality score (AQS) means the numeric score calculated for each RO participant based on its performance on, and reporting of, quality measures and clinical data. The AQS is used to determine an RO participant's quality reconciliation payment amount.

APM means Alternative Payment Model.

ASC means Ambulatory Surgery Center.

Baseline period means the three calendar year period that begins on January 1 no fewer than five years but no more than six years prior to the start of the model performance period during which episodes must initiate in order to be used in the calculation of the national base rates, each RO participant's historical experience adjustment for the PC or TC or both for the model performance period, and the RO participant's case mix adjustment for the PC or TC or both for PY1. The baseline period is January 1, 2017 through December 31, 2019, unless the RO Model is prohibited by law from starting in calendar year (CY) 2022, in which case the baseline period will be delayed based on the new model performance period (for example, if the model performance period starts any time in CY 2023, then the baseline period would be CY 2018 through CY 2020).

Blend means the weight given to an RO participant's historical experience adjustment relative to the geographically-adjusted trended national base rate in the calculation of its participant-specific episode payment amounts.

CAH means Critical Access Hospital.

CEHRT means Certified Electronic Health Record Technology.

Clean period means the 28-day period after an RO episode has ended, during which time an RO participant must bill for medically necessary RT services furnished to the RO beneficiary in accordance with Medicare FFS billing rules.

Core-Based Statistical Area (CBSA) means a statistical geographic area, based on the definition as identified by the Office of Management and Budget, with a population of at least 10,000, which consists of a county or counties anchored by at least one core (urbanized area or urban cluster), plus adjacent counties having a high degree of social and economic integration with the core (as measured through commuting ties with the counties containing the core).

Discount factor means the percentage by which CMS reduces payment of the professional component and technical component.

(1) The reduction of payment occurs after the trend factor, the geographic adjustment, and the RO Model-specific adjustments have been applied, but before beneficiary cost-sharing and standard CMS adjustments, including sequestration, have been applied.

(2) The discount factor does not vary by cancer type.

(3) The discount factor for the professional component is 3.5 percent; the discount factor for the technical component is 4.5 percent.

Dual participant means an RO participant that furnishes both the professional component and technical component of RT services of an RO episode through a freestanding radiation therapy center, identified by a single TIN.

Duplicate RT service means any included RT service that is furnished to an RO beneficiary by an RT provider or RT supplier that is not excluded from participation in the RO Model at § 512.210(b), and that did not initiate the PC or TC of the RO beneficiary's RO episode. Such services are furnished in addition to the RT services furnished by the RO participant that initiated the PC or TC and continues to furnish care to the RO beneficiary during the RO episode.

Episode means the 90-day period of RT services that begins on the date of service that an RT provider or RT supplier that is not an RO participant furnishes an initial treatment planning service to a beneficiary, provided that an RT provider or RT supplier furnishes a technical component RT service to the beneficiary within 28 days of such initial treatment planning service. Additional criteria for constructing episodes to be included in determining the national base rates are set forth in § 512.250.

EOE stands for "end of episode" and means the end of an RO episode.

EUC stands for "extreme and uncontrollable circumstance" and means a circumstance that is beyond the control of one or more RO participants, adversely impacts such RO participants' ability to deliver care in accordance with the RO Model's requirements, and affects an entire region or locale.

HCPCS means Healthcare Common Procedure Coding System.

HOPD means hospital outpatient department.

Included cancer types means the cancer types determined by the criteria set forth in § 512.230, which are included in the RO Model test.

Included RT services means the RT services identified at § 512.235, which are included in the RO Model test.

Incomplete episode means an RO episode that is deemed not to have occurred because:

(1) A Technical participant or a Dual participant does not furnish a technical component to an RO beneficiary within 28 days following a Professional participant or the Dual participant furnishing an initial treatment planning service to that RO beneficiary;

(2) An RO beneficiary ceases to have traditional FFS Medicare as his or her primary payer at any time after the initial treatment planning service is furnished and before the date of service on a claim with an RO Model-specific HCPCS code and an EOE modifier; or

(3) An RO beneficiary switches RT provider or RT supplier before all included RT services in the RO episode have been furnished.

Individual practitioner means a Medicare-enrolled physician (identified by an NPI) who furnishes RT services to Medicare FFS beneficiaries, and has reassigned his or her billing rights to the TIN of an RO participant.

Individual practitioner list means a list of individual practitioners who furnish RT services under the TIN of a Dual participant or a Professional participant, which is annually compiled by CMS and which the RO participant must review, revise, and certify in accordance with § 512.217. The individual practitioner list is used for the RO Model as a Participation List as defined in § 414.1305 of this chapter.

Initial reconciliation means the first reconciliation of a PY that occurs as early as August following the applicable PY.

Legacy CCN means a CMS certification number (CCN) that an RO participant that is a hospital outpatient department (HOPD) or its predecessor(s) previously used to bill Medicare for included RT services but no longer uses to bill Medicare for included RT services.

Legacy TIN means a taxpayer identification number (TIN) that an RO participant that is a PGP, or a freestanding radiation therapy center, or its predecessor(s) previously used to bill Medicare for included RT services but no longer uses to bill Medicare for included RT services.

MIPS means Merit based Incentive Payment System.

Model performance period means the 5 performance years (PYs) during which RO episodes initiate and terminate. CMS will establish the start and end dates of the model performance period for the RO Model through future rulemaking.

National base rate means the total payment amount for the relevant component of an RO episode, before application of the trend factor, discount factor, adjustments, and applicable withholds, for each of the included cancer types.

NPI means National Provider Identifier.

OPPS means outpatient prospective payment system.

Participant-specific professional episode payment means a payment which is calculated by CMS as set forth in § 512.255 and which is paid by CMS to a Professional participant or Dual participant as set forth in § 512.265, for the provision of the professional component to an RO beneficiary during an RO episode.

Participant-specific technical episode payment means a payment which is calculated by CMS as set forth in § 512.255 and which is paid by CMS to a Technical participant or Dual participant in accordance with § 512.265, for the provision of the technical component to an RO beneficiary during an RO episode.

PGP means physician group practice.

PPS means prospective payment system.

Professional component (PC) means the included RT services that may only be furnished by a physician.

Professional participant means an RO participant that is a Medicare-enrolled PGP identified by a single TIN that furnishes only the PC of an RO episode.

PSO means patient safety organization.

PY stands for performance year and means each 12-month period beginning on January 1 and ending on December 31 during the model performance period, unless the model performance period begins on a date other than January 1, in which case, the first performance year (PY1) begins on that date and ends on December 31 of the same year.

QP means Qualifying APM Participants.

Reconciliation payment means a payment made by CMS to an RO participant, as determined in accordance with § 512.285.

Repayment amount means the amount owed by an RO participant to CMS, as determined in accordance with § 512.285.

Reconciliation report means the annual report issued by CMS to an RO participant for each PY, which specifies the RO participant's reconciliation payment amount or repayment amount.

RO beneficiary means a Medicare beneficiary who meets all of the beneficiary inclusion criteria at § 512.215(a) and whose RO episode meets all the criteria defined at § 512.245.

RO episode means the 90-day period that, as set forth in § 512.245, begins on the date of service that a Professional participant or a Dual participant furnishes an initial treatment planning service to an RO beneficiary in a freestanding radiation therapy center or an HOPD, provided that a Technical participant or the same Dual participant furnishes a technical component RT service to the RO beneficiary within 28 days of such RT treatment planning service.

RO participant means a Medicare-enrolled PGP, freestanding radiation therapy center, or HOPD that participates in the RO Model in accordance with § 512.210. An RO participant may be a Dual participant, Professional participant, or Technical participant.

RT provider means a Medicare-enrolled HOPD that furnishes RT services.

RT services are the treatment planning, technical preparation, special services (such as simulation), treatment delivery, and treatment management services associated with cancer treatment that uses high doses of radiation to kill cancer cells and shrink tumors.

RT supplier means a Medicare-enrolled PGP or freestanding radiation therapy center that furnishes RT services.

SOE stands for "start of episode" and means the start of an RO episode.

Stop-loss limit means the set percentage at which loss is limited under the Model used to calculate the stop-loss reconciliation amount.

Stop-loss reconciliation amount means the amount set forth in § 512.285(f) owed by CMS for the loss incurred under the Model to RO participants that have fewer than 60 episodes during the baseline period and were furnishing included RT services before the start of the model performance period in the CBSAs selected for participation.

Technical component (TC) means the included RT services that are not furnished by a physician, including the provision of equipment, supplies, personnel, and administrative costs related to RT services.

Technical participant means an RO participant that is a Medicare-enrolled HOPD or freestanding radiation therapy center, identified by a single CMS Certification Number (CCN) or TIN, which furnishes only the TC of an RO episode.

TIN means Taxpayer Identification Number.

Track One means a track for Professional participants and Dual participants that meet all RO Model requirements as specified in § 512.220, including use of CEHRT.

Track Two means a track for Professional participants and Dual participants that meet all RO Model requirements as specified in § 512.220, except for use of CEHRT.

Track Three means a track for Professional participants and Dual participants who do not meet one or more of the RO Model requirements set forth at § 512.220(a); and for all Technical participants.

Trend factor means an adjustment applied to the national base rates that updates those rates to reflect current trends in the OPPS and PFS rates for RT services.

True-up reconciliation means the process to calculate additional reconciliation payments or repayment amounts for incomplete episodes and duplicate RT services that are identified after the initial reconciliation and after a 12-month claims run-out for all RO episodes initiated in the applicable PY.

[85 FR 61362, Sept. 29, 2020, as amended at 85 FR 86304, Dec. 29, 2020; 86 FR 63994, Nov. 16, 2021; 87 FR 52704, Aug. 29, 2022]

Editorial Note: At 85 FR 86304, Dec. 29, 2020, this section was amended, effective Dec. 4, 2020; however, due to a publication error, the amendments were codified at 86 FR 33902, June 28, 2021.

RO Model Participation

§ 512.210 RO participants and geographic areas.

(a) ***RO participants.*** Unless otherwise specified in paragraph (b) or (c) of this section, any Medicare-enrolled PGP, freestanding radiation therapy center, or HOPD that furnishes included RT services in a 5-digit ZIP Code linked to a CBSA selected for participation to an RO beneficiary for an RO episode that begins and ends during the model performance period must participate in the RO Model.

(b) ***Participant exclusions.*** A PGP, freestanding radiation therapy center, or HOPD is excluded from participation in the RO Model if it:

(1) Furnishes RT services only in Maryland;

(2) Furnishes RT services only in Vermont;

(3) Furnishes RT services only in U.S. Territories;

(4) Is classified as an ambulatory surgery center (ASC), critical access hospital (CAH), or Prospective Payment System (PPS)-exempt cancer hospital; or

(5) Participates in the Pennsylvania Rural Health Model; or

(6) Participates in the Community Transformation Track of the Community Health Access and Rural Transformation (CHART) Model as a participating hospital.

(c) ***Low volume opt-out.*** A PGP, freestanding radiation therapy center, or HOPD that would otherwise be required to participate in the RO Model may choose to opt-out of the RO Model as follows:

(1) If the PGP, freestanding radiation therapy center, or HOPD furnished fewer than 20 episodes in the calendar year that is two years prior to the start of PY1 across all CBSAs selected for participation, it may opt out of the RO Model for PY1.

(2) If the PGP, freestanding radiation therapy center, or HOPD furnished fewer than 20 episodes in the calendar year that is two years prior to the start of PY2 across all CBSAs selected for participation, it may opt out of the RO Model for PY2.

(3) If the PGP, freestanding radiation therapy center, or HOPD furnished fewer than 20 RO episodes in PY1 across all CBSAs selected for participation, and PY1 begins on January 1, it may choose to opt out of the RO Model for PY3. In the event that PY1 begins on a date other than January 1, the PGP, freestanding radiation therapy center, or HOPD may opt-out of the RO Model for PY3 if the total number of furnished episodes of the calendar year in which PY1 began and RO episodes in PY1 is fewer than 20 across all CBSAs selected for participation.

(4) If the PGP, freestanding radiation therapy center, or HOPD furnished fewer than 20 RO episodes in PY2 across all CBSAs selected for participation, it may opt out of the RO Model for PY4.

(5) If the PGP, freestanding radiation therapy center, or HOPD furnished fewer than 20 RO episodes in PY3 across all CBSAs selected for participation, it may opt out of the RO Model for PY5.

(6) At least 30 days prior to the start of each PY, CMS provides notice to RO participants eligible for the low volume opt-out for the upcoming PY of such eligibility. The RO participant must attest that it intends to opt out of the RO Model prior to the start of the upcoming PY.

(7) An entity is not eligible for the low-volume opt out if its current TIN or CCN, or its legacy TIN or legacy CCN, or both were used to bill Medicare for 20 or more episodes or RO episodes, as applicable, of RT services in the two years prior to the applicable PY across all CBSAs selected for participation.

(d) ***Selected CBSAs.*** CMS randomly selects CBSAs to identify RT providers and RT suppliers to participate in the RO Model through a stratified sample design, allowing for participant and comparison groups to contain approximately 30 percent of all episodes in eligible geographic areas (CBSAs).

(e) ***Notice of change in TIN or CCN.*** An RO participant must furnish written notice to CMS in a form and manner specified by CMS at least 90 days before the effective date of any change in TIN or CCN that is used to bill Medicare.

[85 FR 61362, Sept. 29, 2020, as amended at 85 FR 86304, Dec. 29, 2020; 86 FR 63994, Nov. 16, 2021]

Editorial Note: At 85 FR 86304, Dec. 29, 2020, this section was amended, effective Dec. 4, 2020; however, due to a publication error, the amendments were codified at 86 FR 33902, June 28, 2021.

§ 512.215 Beneficiary population.

(a) ***Beneficiary inclusion criteria.*** An individual is an RO beneficiary if:

(1) The individual receives included RT services from an RO participant that billed the SOE modifier for the PC or TC of an RO episode during the Model performance period for an included cancer type; and

(2) At the time that the initial treatment planning service of an RO episode is furnished by an RO participant, the individual:

(i) Is eligible for Medicare Part A and enrolled in Medicare Part B;

(ii) Has traditional FFS Medicare as his or her primary payer (for example, is not enrolled in a PACE plan, Medicare Advantage or another managed care plan, or United Mine Workers insurance); and

(iii) Is not in a Medicare hospice benefit period.

(b) Any individual enrolled in a clinical trial for RT services for which Medicare pays routine costs is an RO beneficiary if the individual satisfies all of the beneficiary inclusion criteria in paragraph (a) of this section.

§ 512.217 Identification of individual practitioners.

(a) ***General.*** Upon the start of each PY, CMS creates and provides to each RO participant that is a PGP or a freestanding radiation therapy center an individual practitioner list identifying by NPI each individual practitioner associated with the RO participant. For RO participants that begin participation in the RO Model after the start of a PY, but at least 30 days prior to the last QP determination date as specified at § 414.1325 of this chapter, CMS creates and provides an individual practitioner list to that RO participant.

(b) ***Review of individual practitioner list.*** Up until the last QP determination date as specified at § 414.1325 of this chapter, the RO participant must review the individual practitioner list, correct any inaccuracies in accordance with paragraph (d) of this section, and certify the list (as corrected, if applicable) in a form

and manner specified by CMS and in accordance with paragraph (c) of this section. The RO participant may correct any inaccuracies in its individual practitioner list until the last QP determination date as specified at § 414.1325 of this chapter. Any Dual participant, Professional participant, or Technical participant that is a freestanding radiation therapy center and joins the RO Model after the start of a PY must review and certify its individual practitioner list by the last QP determination date as specified at § 414.1325 of this chapter.

(c) ***List certification.***

(1) Up until the last QP determination date as specified at § 414.1325 of this chapter, an individual with the authority to legally bind the RO participant must certify the accuracy, completeness, and truthfulness of the individual practitioner list to the best of his or her knowledge, information, and belief.

(2) All Medicare-enrolled individual practitioners that have reassigned their right to receive Medicare payment for provision of RT services to the TIN of the RO participant must be included on the RO participant's individual practitioner list and each individual practitioner must agree to comply with the requirements of the RO Model before the RO participant certifies the individual practitioner list.

(3) If the RO participant does not certify the individual practitioner list in PY2 through PY5:

(i) Eligible clinicians in the RO Model will not be considered participants in a MIPS APM for purposes of MIPS reporting and scoring rules;

(ii) Eligible clinicians in the RO Model will not have Qualifying APM Participant ("QP") determinations made based on their participation in the RO Model; and

(d) ***Changes to the individual practitioner list*** —

(1) ***Additions.***

(i) An RO participant must notify CMS of an addition to its individual practitioner list when an eligible clinician reassigns his or her rights to receive payment from Medicare to the RO participant. The notice must be submitted in the form and manner specified by CMS up until the last QP determination date as specified at § 414.1325 of this chapter.

(ii) If the RO participant timely submits notice to CMS, then the addition of an individual practitioner to the RO participant's individual practitioner list is effective on the date specified in the notice furnished to CMS, but no earlier than 30 days before the date of the notice. If the RO participant fails to submit timely notice to CMS, then the addition of an individual practitioner to the individual practitioner list is effective on the date of the notice.

(2) ***Removals.***

(i) An RO participant must notify CMS when an individual on the RO participant's individual practitioner list ceases to be an individual practitioner up until the last QP determination date as specified at § 414.1325 of this chapter. The notice must be submitted in the form and manner specified by CMS.

(ii) The removal of an individual practitioner from the RO participant's individual practitioner list is effective on the date specified in the notice furnished to CMS. If the RO participant fails to submit a timely notice of the removal, then the removal is effective on the date that the individual ceases to be an individual practitioner.

(e) ***Update to Medicare enrollment information.*** The RO participant must ensure that all changes to enrollment information for an RO participant and its individual practitioners, including changes to reassignment of the right to receive Medicare payment, are reported to CMS consistent with § 424.516 of this chapter.

[85 FR 61362, Sept. 29, 2020, as amended at 85 FR 86304, Dec. 29, 2020; 86 FR 63995, Nov. 16, 2021]

Editorial Note: At 85 FR 86304, Dec. 29, 2020, this section was amended, effective Dec. 4, 2020; however, due to a publication error, the amendments were codified at 86 FR 33902, June 28, 2021.

§ 512.220 RO participant compliance with RO Model requirements.

(a) ***RO participant-specific requirements.***

(1) An RO participant must satisfy the requirements of this section to be included in Track One under the RO Model in a particular PY. An RO participant that meets all of these RO Model requirements in a particular PY, excluding use of CEHRT, will be in Track Two for such PY. An RO participant that does not meet one or more of the RO Model requirements in paragraph (a) of this section in a particular PY will be in Track Three for such PY.

(2) Each Professional participant and Dual participant must ensure its individual practitioners:

(i) Starting in PY1, discuss goals of care with each RO beneficiary before initiating treatment and communicate to the RO beneficiary whether the treatment intent is curative or palliative;

(ii) Starting in PY1, adhere to nationally recognized, evidence-based clinical treatment guidelines when appropriate in treating RO beneficiaries or, alternatively, document in the medical record the extent of and rationale for any departure from these guidelines;

(iii) Starting in PY1, assess each RO beneficiary's tumor, node, and metastasis cancer stage for the CMS-specified cancer diagnoses;

(iv) Starting in PY1, assess the RO beneficiary's performance status as a quantitative measure determined by the physician;

(v) Starting in PY1, send a treatment summary to each RO beneficiary's referring physician within 3 months of the end of treatment to coordinate care;

(vi) Starting in PY1, discuss with each RO beneficiary prior to treatment delivery his or her inclusion in, and cost-sharing responsibilities under, the RO Model; and

(vii) Starting in PY1, perform and document Peer Review (audit and feedback on treatment plans) before 25 percent of the total prescribed dose has been delivered and within 2 weeks of the start of treatment for:

(A) 50 percent of new patients in PY1,

(B) 55 percent of new patients in PY2,

(C) 60 percent of new patients in PY3,

(D) 65 percent of new patients in PY4,

(E) 70 percent of new patients in PY5.

(3) Starting in PY1, at such times and in the form and manner specified by CMS, each Technical participant and Dual participant must annually attest to whether it actively participates with a AHRQ-listed patient safety organization (PSO). Examples include maintaining a contractual or similar relationship with a PSO for the receipt and review of patient safety work product.

(b) ***CEHRT.***

(1) RO participants must use CEHRT, and ensure that their individual practitioners use CEHRT, in a manner sufficient to meet the applicable requirements of the Advanced APM criteria as specified at § 414.1415(a)(1)(i) of this chapter.

(2) Within 30 days of the start of PY1 and each subsequent PY, the RO participant must certify its use of CEHRT throughout such PY in a manner sufficient to meet the requirements set forth in § 414.1415(a)(1)(i) of this chapter.

(3) An RO participant that joins the RO Model at any time during an ongoing PY must certify their use of CEHRT by the last QP determination date as specified at § 414.1325 of this chapter.

[85 FR 61362, Sept. 29, 2020, as amended at 85 FR 86304, Dec. 29, 2020; 86 FR 63995, Nov. 16, 2021]

Editorial Note: At 85 FR 86304, Dec. 29, 2020, this section was amended, effective Dec. 4, 2020; however, due to a publication error, the amendments were codified at 86 FR 33902, June 28, 2021.

§ 512.225 Beneficiary notification.

(a) ***General.*** Starting in PY1, each Professional participant and Dual participant must notify each RO beneficiary to whom it furnishes included RT services—

(1) That the RO participant is participating in the RO Model;

(2) That the RO beneficiary has the opportunity to decline claims data sharing for care coordination and quality improvement purposes. If an RO beneficiary declines claims data sharing for care coordination and quality improvement purposes, then the RO participant must inform CMS within 30 days of receiving notification from the RO beneficiary that the beneficiary is declining to have his or her claims data shared in that manner; and,

(3) Of the RO beneficiary's cost-sharing responsibilities.

(b) ***Form and manner of notification.*** Notification of the information specified in paragraph (a) of this section must be carried out by an RO participant by providing each RO beneficiary with a CMS-developed standardized written notice during the RO beneficiary's initial treatment planning session. The RO participants must furnish the notice to the RO beneficiary in the form and manner specified by CMS.

(c) ***Applicability of general Innovation Center provisions.*** The beneficiary notifications under this section are not descriptive model materials and activities under § 512.120(c). The requirement described in § 512.120(c)(2) does not apply to the standardized written notice described in paragraph (b) of this section.

SCOPE OF RO EPISODES BEING TESTED

§ 512.230 Criteria for determining cancer types.

(a) ***Included cancer types.*** CMS includes in the RO Model cancer types that satisfy the following criteria:

(1) The cancer type is commonly treated with radiation per nationally recognized, evidence-based clinical treatment guidelines;

(2) The cancer type has one or more associated current ICD-10 codes that have demonstrated pricing stability; and

(3) The Secretary has not determined that the cancer type is not suitable for inclusion in the RO Model.

(b) ***Removing cancer types.*** CMS removes cancer types in the RO Model if it determines:

(1) That there is a ≥10 percent error in established national base rates; or

(2) The cancer type does not meet the criteria set forth in paragraph (a) of this section.

(c) ***ICD-10 codes for included cancer types.*** CMS displays on the RO Model website no later than 30 days prior to each PY the ICD-10 diagnosis codes associated with each included cancer type.

[85 FR 61362, Sept. 29, 2020, as amended at 86 FR 63996, Nov. 16, 2021]

§ 512.235 Included RT services.

(a) Only the following RT services furnished using an included modality identified at § 512.240 for an included cancer type are included RT services that are paid for by CMS under § 512.265:

(1) Treatment planning;

(2) Technical preparation and special services;

(3) Treatment delivery; and,

(4) Treatment management.

(b) All other RT services furnished by an RO participant during the Model performance period are subject to Medicare FFS payment rules.

§ 512.240 Included modalities.

The modalities included in the RO Model are 3-dimensional conformal RT (3DCRT), intensity-modulated RT (IMRT), stereotactic radiosurgery (SRS), stereotactic body RT (SBRT), proton beam therapy (PBT), and image-guided radiation therapy (IGRT).

[86 FR 63996, Nov. 16, 2021]

§ 512.245 Included RO episodes.

(a) ***General.*** Any RO episode that begins on or after the first day of the model performance period and ends on or before the last day of the model performance period is included in the model performance period.

(b) ***Death or election of hospice benefit.*** An RO episode is included in, and paid for under, the RO Model if the RO beneficiary dies after the TC of an RO episode has been initiated, or if the RO beneficiary elects the Medicare hospice benefit after the initial treatment planning service, provided that the TC is initiated within 28 days following the initial treatment planning service. Each RO participant will receive both installments of the episode payment under such circumstances, regardless of whether the RO beneficiary dies or elects the Medicare hospice benefit before the relevant course of RT treatment has ended.

(c) ***Clean periods.*** An RO episode must not be initiated for the same RO beneficiary during a clean period.

[85 FR 61362, Sept. 29, 2020, as amended at 85 FR 86305, Dec. 29, 2020; 86 FR 63996, Nov. 16, 2021]

Editorial Note: At 85 FR 86305, Dec. 29, 2020, this section was amended, effective Dec. 4, 2020; however, due to a publication error, the amendments were codified at 86 FR 33902, June 28, 2021.

PRICING METHODOLOGY

§ 512.250 Determination of national base rates.

CMS determines a national base rate for the PC and TC for each included cancer type.

(a) National base rates are the historical average cost for an episode of care for each of the included cancer types prior to the Model performance period.

(b) National base rates are determined in the following manner:

(1) CMS excludes from episode pricing and RO episode pricing any claim containing an RT service furnished:

(i) In Maryland, Vermont, or any of the U.S. Territories;

(ii) In the inpatient setting;

(iii) By an entity classified as an ASC, CAH, or PPS-exempt cancer hospital; or

(iv) By an HOPD participating in the Pennsylvania Rural Health Model at the time the RT service was furnished.

(2) CMS excludes the following episodes from the determination of the national base rates:

(i) Episodes that are not linked to a CBSA selected for participation in the RO Model;

(ii) Episodes that are not attributed to an RT provider or RT supplier;

(iii) Episodes that are not assigned an included cancer type; or

(iv) Episodes for which the total allowed amount for RT services listed on claims used to calculate an episode's payment amount is not greater than $0.

(3) CMS calculates the episode amount CMS paid on average to RT providers and RT suppliers for the PC and TC for each of the included cancer types in the HOPD setting, creating the RO Model's national base rates.

[85 FR 61362, Sept. 29, 2020, as amended at 86 FR 63996, Nov. 16, 2021]

§ 512.255 Determination of participant-specific professional episode payment and participant-specific technical episode payment amounts.

(a) Thirty days before the start of each PY, CMS provides each RO participant its case mix and historical experience adjustments for both the PC and TC as calculated in paragraphs (c)(3) and (4) of this section. If an RO participant is not eligible to receive a historical experience adjustment or case mix adjustment as described under paragraph (c)(7) of this section, then CMS provides a zero value for those adjustments.

(b) Any episode used to calculate the participant-specific professional episode payment amounts and the participant-specific technical episode payment amounts for an RO participant is subject to the exclusions described in § 512.250(b)(1) and (2).

(c) CMS calculates the participant-specific professional episode payment amounts and participant-specific technical episode payment amounts for each included cancer type using the following:

(1) ***Trend factors.*** For every PY, CMS adjusts the national base rates for the PC and TC of each cancer type by calculating a separate trend factor for the PC and TC of each included cancer type.

(2) ***Geographic adjustment.*** CMS adjusts the trended national base rates prior to applying each RO participant's case mix and historical experience, and prior to applying the discounts and withholds, for local cost and wage indices based on where RT services are furnished, as described by existing geographic adjustment processes in the OPPS and PFS.

(3) ***Case mix adjustment.*** CMS establishes and applies a case mix adjustment to the national base rate after the trend factor and geographic adjustment have applied. The case mix adjustment reflects episode or RO episode characteristics that may be beyond the control of RO participants such as cancer type, age, sex, presence of a major procedure, death during the episode, and presence of chemotherapy.

(4) ***Historical experience adjustment.*** CMS establishes and applies a historical experience adjustment to the national base rate after the trend factor, geographic adjustment, and case mix adjustment have been applied. The historical experience adjustments reflect each RO participant's actual historical experience.

(5) ***Blend.*** CMS blends each RO participant's historical experience adjustment and the geographically-adjusted trended national base rate. The blend for RO participants with a professional historical experience adjustment or technical historical experience adjustment with a value equal to or less than zero is 90/10, meaning the calculation of the participant-specific episode payment amount is weighted according to 90 percent of the RO participant's historical experience adjustment and 10 percent of the geographically-adjusted trended national base for PY1 through PY5. The blend for RO participants with a professional historical experience adjustment or technical historical experience adjustment of more than zero is 90/10 in PY1, 85/15 in PY2, 80/20 in PY3, 75/25 in PY4, and 70/30 in PY5.

(6) ***Changes in business structure.***

(i) RO participants must notify CMS in writing of a merger, acquisition, or other new clinical or business relationship, at least 90 days before the date of the change as described in § 424.516.

(ii) CMS updates case mix and historical experience adjustments according to the relevant treatment history that applies as a result of a merger, acquisition, or other new clinical or business relationship in the RO participant's case mix and historical experience adjustment calculations from the effective date of the change.

(7) ***Adjustments for RO participants with fewer than 60 episodes during the baseline period.***

(i) RO participants that have fewer than 60 episodes in the baseline period do not receive a historical experience adjustment during the model performance period.

(ii) RO participants that have fewer than 60 episodes in the baseline period do not receive a case mix adjustment for PY1.

(iii) RO participants that have fewer than 60 episodes in the baseline period that continue to have fewer than 60 episodes in the rolling 3-year period used to determine the case mix adjustment for each PY and that have never received a case mix adjustment do not receive a case mix adjustment for that PY.

(iv) RO participants that have fewer than 60 episodes in the baseline period and were furnishing included RT services in the CBSAs selected for participation before the start of the model performance period are eligible to receive a stop-loss reconciliation amount, if applicable, as described in § 512.285(f).

(8) ***Discount factor.*** CMS reduces each episode payment by the discount factor after applying the trend factor, geographic adjustment, and case mix and historical experience adjustments to the national base rate.

(9) ***Incorrect payment withhold.*** To account for duplicate RT services and incomplete episodes:

(i) CMS withholds from each RO participant 1 percent from each episode payment, after applying the trend factor, geographic adjustment, case mix and historical experience adjustments, and discount to the national base rate.

(ii) CMS determines during the annual reconciliation process set forth at § 512.285 whether an RO participant is eligible to receive a portion or all of the withheld amount or whether any payment is owed to CMS.

(10) ***Quality withhold.*** In accordance with § 414.1415(b)(1) of this chapter, CMS withholds 2 percent from each professional episode payment after applying the trend factor, geographic adjustment, case mix and historical experience adjustments, and discount factor to the national base rate. RO participants may earn back this withhold, in part or in full, based on their AQS.

(11) ***Patient experience withhold.*** Starting in PY3,

(i) CMS withholds 1 percent from each technical episode payment after applying the trend factor, geographic adjustment, case mix and historical experience adjustments, and discount factor to the national base rate.

(ii) RO participants may earn back their patient-experience withhold, in part or in full, based on their results from the CAHPS® Cancer Care Radiation Therapy survey.

(12) ***Coinsurance.*** RO participants may collect beneficiary coinsurance payments for services furnished under the RO Model in multiple installments under a payment plan.

(i) The availability of payment plans may not be used as a marketing tool to influence beneficiary choice of health care provider.

(ii) RO participants offering a payment plan may inform the RO beneficiary of the availability of the payment plan prior to or during the initial treatment planning session and as necessary thereafter.

(iii) The beneficiary coinsurance payment equals 20 percent of the episode payment amount to be paid to the RO participant(s) prior to the application of sequestration for the billed RO Model-specific HCPCS code with a SOE modifier and for the billed RO Model-specific HCPCS code with an EOE modifier for the PC and TC, except as provided in paragraph (c)(12)(iv) and(v) of this section.

(iv) In the case of incomplete episodes, the beneficiary coinsurance payment equals 20 percent of the FFS amounts that would have been paid in the absence of the RO Model for the services furnished by the RO participant that initiated the PC and the RO participant that initiated the TC (if applicable).

(v) In the case of duplicate RT services, the beneficiary coinsurance payment equals 20 percent of the episode payment amount to be paid to the RO participant(s) per § 512.255(c)(12)(iii) and 20 percent of the FFS amount to the RT provider and/or RT supplier furnishing one or more duplicate RT services.

(13) ***Sequestration.*** In accordance with applicable law, CMS deducts a percentage from each episode payment after applying the trend factor, geographic adjustment, case mix and historical experience adjustments, discount, withholds, and coinsurance to the national base rate.

(14) ***Modifications to the participant-specific adjustments for changes in TINs or CCNs.***

(i) CMS calculates the RO participant's case mix adjustments in accordance with paragraph (c)(3) of this section based on all episodes and RO episodes, as applicable, attributed to the RO participant's legacy TIN(s) or legacy CCN(s), and current TIN or CCN, during the 3-year period that determines the case mix adjustment for each PY.

(ii) CMS calculates the RO participant's historical experience adjustments in accordance with paragraph (c)(4) of this section based on all episodes attributed to the RO participant's legacy TIN(s) or legacy CCN(s), and current TIN or CCN, during the baseline period.

[85 FR 61362, Sept. 29, 2020, as amended at 85 FR 86305, Dec. 29, 2020; 86 FR 63996, Nov. 16, 2021]

Editorial Note: At 85 FR 86305, Dec. 29, 2020, this section was amended, effective Dec. 4, 2020; however, due to a publication error, the amendments were codified at 86 FR 33902, June 28, 2021.

BILLING AND PAYMENT

§ 512.260 Billing.

(a) ***Reassignment of billing rights.*** Each Professional participant and Dual participant must ensure that its individual practitioners reassign their billing rights to the TIN of the Professional participant or Dual participant.

(b) ***Billing under the RO Model.***

(1) Professional participants and Dual participants must bill an RO Model-specific HCPCS code and a SOE modifier to indicate that the treatment planning service has been furnished and that an RO episode has been initiated.

(2) Dual participants and Technical participants must bill an RO Model-specific HCPCS code and SOE modifier to indicate that a treatment delivery service was furnished.

(3) RO participants must bill the same RO Model-specific HCPCS code that initiated the RO episode and an EOE modifier to indicate that the RO episode has ended.

(4) RO participants may submit a claim with an EOE modifier only after the RT course of treatment has ended, except that such claim must not be submitted earlier than 28 days after the date of the initial treatment planning service.

(c) ***Billing for RT services performed during a clean period.*** RO participants must bill for any medically necessary RT services furnished to an RO beneficiary during a clean period in accordance with existing FFS billing processes in the OPPS and PFS.

(d) ***Submission of no-pay claims.*** RO participants must submit no-pay claims for any medically necessary included RT services furnished to an RO beneficiary during an RO episode pursuant to existing FFS billing processes in the OPPS and PFS.

§ 512.265 Payment.

(a) ***Payment for episodes.*** CMS pays an RO participant for all included RT services furnished to an RO beneficiary during a completed RO episode as follows:

(1) CMS pays a Professional participant a participant-specific professional episode payment for the professional component furnished to an RO beneficiary during an RO episode.

(2) CMS pays a Technical participant a participant-specific technical episode payment for the technical component furnished to an RO beneficiary during an RO episode.

(3) CMS pays a Dual participant a participant-specific professional episode payment and a participant-specific technical episode payment for the professional component and technical component furnished to an RO beneficiary during an RO episode.

(b) ***Payment installments.*** CMS makes each of the payments described in paragraph (a) of this section in two equal installments, as follows:

(1) CMS pays one-half of a participant-specific professional episode payment to a Professional participant or Dual participant or one-half of the participant-specific technical episode payment to a Technical participant or Dual participant after the RO participant bills an RO Model-specific HCPCS code with a SOE modifier.

(2) CMS pays the remaining half of a participant-specific professional episode payment to a Professional participant or Dual participant or one-half of the participant-specific technical episode payment to a Technical participant or Dual participant after the RO participant bills an RO Model-specific HCPCS code with an EOE modifier.

(c) ***Duplicate RT services.*** Duplicate RT services are reimbursed at the FFS amount, whether or not the RT provider or RT supplier that furnished such services is an RO participant.

§ 512.270 Treatment of add-on payments under existing Medicare payment systems.

(a) CMS does not make separate Medicare FFS payments to RO participants for any included RT services that are furnished to an RO beneficiary during an RO episode.

(b) An RO participant may receive Medicare FFS payment for items and services furnished to an RO beneficiary during an RO episode, provided that any such other item or service is not an included RT service.

DATA REPORTING

§ 512.275 Quality measures, clinical data, and reporting.

(a) ***Data privacy compliance.*** The RO participant must—

(1) Comply with all applicable laws pertaining to any patient-identifiable data requested from CMS under the terms of the Innovation Center model, including any patient-identifiable derivative data, as well as the terms of any attestation or agreement entered into by the RO participant with CMS as a condition of receiving that data. Such laws may include, without limitation, the privacy and security rules promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as modified, and the Health Information Technology for Economic and Clinical Health Act (HITECH).

(2) Contractually bind all downstream recipients of CMS data to the same terms and conditions to which the RO participant was itself bound in its agreements with CMS as a condition of the downstream recipient's receipt of the data from the RO participant.

(b) ***RO participant public release of patient de-identified information.*** The RO participant must include the disclaimer codified at § 512.120(c)(2) on the first page of any publicly-released document, the contents of which materially and substantially references or is materially and substantially based upon the RO participant's participation in the RO Model, including but not limited to press releases, journal articles, research articles, descriptive articles, external reports, and statistical/analytical materials.

(c) ***Reporting quality measures and clinical data elements.*** In addition to reporting described in other provisions in this part, Professional participants and Dual participants must report selected quality measures on all patients and clinical data elements describing cancer stage, disease characteristics, treatment intent, and specific treatment plan information on beneficiaries treated for specified cancer types, in the form, manner, and at a time specified by CMS.

(d) ***Technical participants and reporting of quality measures and clinical data elements.*** Technical participants that are freestanding radiation therapy centers and also begin furnishing the professional component during the model performance period must:

(1) Notify CMS no later than 30 days after the technical participant begins furnishing the professional component, in a form and manner specified by CMS; and

(2) Report quality measures and clinical data elements by the next submission period, as described in paragraph (c) of this section.

[85 FR 61362, Sept. 29, 2020, as amended at 86 FR 63996, Nov. 16, 2021]

MEDICARE PROGRAM WAIVERS

§ 512.280 RO Model Medicare program waivers.

(a) ***General.*** The Secretary may waive certain requirements of title XVIII of the Act as necessary solely for purposes of testing of the RO Model. Such waivers apply only to the participants in the RO Model.

(b) ***Hospital Outpatient Quality Reporting (OQR) Program.*** CMS waives the application of the Hospital OQR Program 2.0 percentage point reduction under section 1833(t)(17) of the Act for only those Ambulatory Payment Classifications (APCs) that include only RO Model-specific HCPCS codes during the Model performance period.

(c) ***Merit-based Incentive Payment System (MIPS).*** CMS waives the requirement under section 1848(q)(6)(E) of the Act and § 414.1405(e) of this chapter to apply the MIPS payment adjustment factor, and, as applicable, the additional MIPS payment adjustment factor (collectively referred to as the MIPS payment adjustment factors) to the TC of RO Model payments to the extent that the MIPS payment adjustment factors would otherwise apply to the TC of RO Model payments.

(d) ***APM Incentive Payment.*** CMS waives the requirements of § 414.1450(b) of this chapter such that technical component payment amounts under the RO Model shall not be considered in calculation of the aggregate payment amount for covered professional services as defined in section 1848(k)(3)(A) of the Act for the APM Incentive Payment made under § 414.1450(b)(1) of this chapter.

(e) ***PFS Relativity Adjuster.*** CMS waives the requirement to apply the PFS Relativity Adjuster to RO Model-specific APCs for RO participants that are non-excepted off-campus provider-based departments (PBDs) identified by section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114-74), which amended section 1833(t)(1)(B)(v) and added paragraph (t)(21) to the Social Security Act.

(f) ***General payment waivers.*** CMS waives the following sections of the Act solely for the purposes of testing the RO Model:

(1) 1833(t)(1)(A).

(2) 1833(t)(16)(D).

(3) 1848(a)(1).

(4) [Reserved].

(5) 1869 claims appeals procedures.

[85 FR 61362, Sept. 29, 2020, as amended at 86 FR 63997, Nov. 16, 2021]

RECONCILIATION AND REVIEW PROCESS

§ 512.285 Reconciliation process.

(a) ***General.*** CMS conducts an initial reconciliation and a true-up reconciliation for each RO participant for each PY in accordance with this section.

(b) ***Annual reconciliation calculations.***

(1) To determine the reconciliation payment or the repayment amount based on RO episodes initiated in a PY, CMS performs the following steps:

(i) CMS calculates an RO participant's incorrect episode payment reconciliation amount as described in paragraph (c) of this section.

(ii) CMS calculates the RO participant's quality reconciliation amount as described in paragraph (d) of this section, if applicable.

(iii) CMS calculates the RO participant's patient experience reconciliation amount, as described in paragraph (e) of this section, if applicable.

(iv) CMS calculates the stop-loss reconciliation amount, as described in paragraph (f) of this section, if applicable.

(v) CMS adds, as applicable, the incorrect episode payment reconciliation amount, any quality reconciliation payment amount, any patient experience reconciliation amount, and any stop-loss reconciliation payment amount. The sum of these amounts results in a reconciliation payment or repayment amount.

(2) CMS calculations use claims data available at the time of reconciliation.

(c) ***Incorrect episode payment reconciliation amount.*** CMS calculates the incorrect episode payment reconciliation amount as follows:

(1) ***Total incorrect payment withhold amount.*** CMS calculates the total incorrect payment withhold amount by adding the incorrect payment withhold amount for each episode initiated in the PY.

(2) ***Total duplicate RT services amount.*** CMS calculates the total duplicate RT services amount by adding all FFS amounts for duplicate RT services furnished during each episode initiated in the PY. The duplicate RT services amount is capped for each episode and will not be more than the participant-specific professional episode payment amount or participant-specific technical episode payment amount received by the RO participant for an RO episode, even if the duplicate RT services amount exceeds the participant-specific professional episode payment amount or the participant-specific technical episode payment amount.

(3) ***Total incomplete episode amount.*** For incomplete episodes initiated in the PY, CMS determines the total incomplete episode amount by calculating the difference between the following amounts:

(i) The sum of all FFS amounts that would have been paid to the RO participant in the absence of the RO Model for any included RT services furnished during such incomplete episodes, as determined by no-pay claims. CMS owes this sum to the RO participant for such incomplete episodes.

(ii) The sum of the participant-specific episode payment amounts paid to the RO participant for such incomplete episodes initiated in the PY.

(4) ***Total incorrect episode payment amount.*** CMS calculates the total incorrect episode payment amount as follows:

(i) If the sum described in paragraph (c)(3)(i) of this section is more than the sum described in paragraph (c)(3)(ii) of this section, the difference is subtracted from the total duplicate RT services amount described in paragraph (c)(2) of this section and the resulting amount is the total incorrect episode payment amount.

(ii) If the sum described in paragraph (c)(3)(i) of this section is less than the sum described in paragraph (c)(3)(ii) of this section, the difference is added to the total duplicate RT services amount described in paragraph (c)(2) of this section and the resulting amount is the total incorrect episode payment amount.

(5) ***Incorrect episode payment reconciliation amount.*** If the total incorrect episode payment amount represents money owed by the RO participant to CMS, CMS subtracts the total incorrect episode payment amount from the total incorrect payment withhold amount. In the case that the total incorrect episode payment amount represents money owed by CMS to the RO participant, CMS adds the total incorrect episode payment amount to the total incorrect payment withhold amount. The resulting amount is the RO participant's incorrect episode payment reconciliation amount.

(d) ***Quality reconciliation payment amount.*** For Professional participants and Dual participants, CMS determines the quality reconciliation payment amount for each PY by multiplying the participant's AQS (as a percentage) by the total quality withhold amount for all RO episodes initiated during the PY.

(e) ***Patient experience reconciliation amount.*** For PY3 and subsequent PYs, CMS determines the patient experience reconciliation amount for RO participants by multiplying the participant's AQS (as a percentage) by the total patient experience withhold amount for all RO episodes initiated during the PY.

(f) ***Stop-loss reconciliation amount.*** CMS determines the stop-loss reconciliation amount for RO participants that have fewer than 60 episodes during the baseline period and were furnishing included RT services before the start of the model performance period in the CBSAs selected for participation by—

(1) Using no-pay claims, CMS calculates the total FFS amount by summing the FFS amounts that would have been paid to the RO participant in the absence of the RO Model for all included RT services furnished during the RO episodes initiated in the PY; and

(2) CMS calculates the sum of all participant-specific professional episode payments and participant-specific technical episode payments paid to the RO participant for the RO episodes initiated in the PY.

(3) If the total FFS amount exceeds the sum of the participant-specific episode payment amounts for the PY by more than 20 percent then CMS owes the RO participant the amount that exceeds 20 percent, either increasing the amount of the RO participant's reconciliation payment or reducing the amount of the RO's participant's reconciliation repayment.

(g) ***True-up reconciliation.*** CMS conducts a true-up reconciliation in the same manner described in paragraph (b) of this section (except that the quality reconciliation payment amount and the patient experience reconciliation amount are not calculated) to determine any additional reconciliation payment or repayment amount that are identified using 12-months of claims run-out.

(h) ***Reconciliation report.*** CMS issues each RO participant a reconciliation report for each PY. Each reconciliation report contains the following:

(1) The RO participant's reconciliation payment or repayment amount, if any, for the relevant PY.

(2) Any additional reconciliation payment or repayment amount owed for a previous PY as a result of the true-up reconciliation.

(3) The net reconciliation payment or repayment amount owed.

(i) ***Payment of amounts owed.***

(1) CMS issues a reconciliation payment to the RO participant in the amount specified in the reconciliation report 30 days after the reconciliation report is deemed final.

(2) The RO participant must pay a repayment amount to CMS in the amount specified in the reconciliation report by a deadline specified by CMS. If the RO participant fails to timely pay the full repayment amount, CMS recoups the repayment amount from any payments otherwise owed by CMS to the RO participant, including Medicare payments for items and services unrelated to the RO Model.

(3) No coinsurance is owed by an RO beneficiary with respect to any repayment amount or reconciliation payment.

[85 FR 61362, Sept. 29, 2020, as amended at 85 FR 86305, Dec. 29, 2020; 86 FR 63997, Nov. 16, 2021]

Editorial Note: At 85 FR 86305, Dec. 29, 2020, this section was amended, effective Dec. 4, 2020; however, due to a publication error, the amendments were codified at 86 FR 33902, June 28, 2021.

§ 512.290 Timely error notice and reconsideration review process.

(a) ***Timely error notice.*** Subject to the limitations on review in § 512.170, an RO participant that identifies and wishes to contest a suspected error in the calculation of its reconciliation payment or repayment amount or AQS must provide written notice of the suspected calculation error to CMS within 45 days of the date of the reconciliation report. Such timely error notice must be in a form and manner specified by CMS. RO participants are not permitted to contest the RO Model pricing methodology or AQS methodology.

(1) Unless a timely error notice is received by CMS within 45 days of the date of issuance of a reconciliation report, the reconciliation payment or repayment amount determination specified in that reconciliation report is deemed binding and not subject to further review.

(2) If CMS receives a timely error notice, then CMS responds in writing within 30 days either to confirm that there was an error in the calculation or to verify that the calculation is correct. CMS may extend the deadline for its response upon written notice to the RO participant.

(3) Only the RO participant may use the timely error notice process described in this paragraph and the reconsideration review process described in paragraph (b) of this section.

(b) ***Reconsideration review*** —

(1) ***Reconsideration request by an RO participant.***

(i) If the RO participant is dissatisfied with CMS' response to the timely error notice, then the RO participant may request a reconsideration review as specified in paragraph (b)(2) of this section.

(ii) If CMS does not receive a request for reconsideration from the RO participant within 10 days of the issue date of CMS' response to the RO participant's timely error notice, then CMS' response to the timely error notice is deemed binding and not subject to further review.

(2) ***Submission of a reconsideration request*** —

(i) ***Information needed in the reconsideration request.*** The reconsideration review request must—

(A) Provide a detailed explanation of the basis for the dispute; and

(B) Include supporting documentation for the RO participant's assertion that CMS or its representatives did not accurately calculate the reconciliation payment or repayment amount or AQS in accordance with the terms of this subpart.

(3) ***Form, manner, and deadline for submission of the reconsideration request.*** The information specified in paragraph (b)(2)(i) of this section must be submitted—

(i) In a form and manner specified by CMS; and

(ii) Within 10 days of the date of the CMS response described in paragraph (a)(2) of this section.

(4) ***Designation of and notification from a CMS-designated reconsideration official.***

(i) ***Designation of reconsideration official.*** CMS designates a reconsideration official who—

(A) Is authorized to receive such requests; and

(B) Was not involved in the responding to the RO participant's timely error notice.

(ii) ***Notification to the RO participant.*** The CMS-designated reconsideration official makes reasonable efforts to notify the RO participant and CMS in writing within 15 days of receiving the RO participant's reconsideration review request of the following:

(A) The issue(s) in dispute;

(B) The briefing schedule; and

(C) The review procedures.

(5) ***Resolution review.*** The CMS reconsideration official makes all reasonable efforts to complete the on-the-record resolution review and issue a written determination no later than 60 days after the submission of the final position paper in accordance with the reconsideration official's briefing schedule.

§ 512.292 Overlap with other models tested under Section 1115A and CMS programs.

Participant-specific professional episode payments and Participant-specific technical episode payments made under the RO Model are not adjusted to reflect payments made under models being tested under 1115A of the Act or the Medicare Shared Savings Program under section 1899 of the Act.

[86 FR 63997, Nov. 16, 2021]

§ 512.294 Extreme and uncontrollable circumstances.

(a) ***General.*** If CMS determines that there is an EUC pursuant to paragraph (b) of this section, CMS may grant RO participants exceptions to the RO Model requirements under paragraph (c) of this section and revise the RO Model's pricing methodology under paragraphs (e) and (f) of this section.

(b) ***Determination factors.*** CMS determines whether there is an EUC based on the following factors:

(1) Whether the RO participants are furnishing services within a geographic area considered to be within an “emergency area” during an “emergency period” as defined in section 1135(g) of the Social Security Act;

(2) Whether the geographic area within a county, parish, U.S. territory, or tribal government designated under the Stafford Act served as a condition precedent for the Secretary's exercise of the 1135 waiver authority, or the National Emergencies Act; or

(3) Whether a state of emergency has been declared in the geographic area.

(c) ***Modified requirements.*** CMS may grant RO Participants exceptions to the following RO Model requirements:

(1) ***Reporting requirements.*** CMS may delay or exempt RO participants from one or more of the RO Model's quality measure or clinical data element reporting requirements if an EUC impacts the RO participants' ability to comply with quality measure or clinical data element reporting requirements.

(2) ***Other requirements.*** CMS may issue a notice on the RO Model website that may waive compliance with or modify the following RO Model requirements:

(i) The requirement set forth at § 512.220(a)(2)(vii) that RO participants provide Peer Review (audit and feedback on treatment plans).

(ii) The requirement set forth at § 512.220(a)(3) that RO participants actively engage with an AHRQ-listed patient safety organization (PSO).

(d) ***Model performance period.*** If CMS determines that the EUC affects the United States and if CMS determines that the EUC would impact RO participants' ability to implement the requirements of the RO Model prior to the start of the model performance period, CMS may amend the model performance period.

(e) ***Trend factor.*** If CMS determines that the EUC affects the entire United States, and if CMS determines that as a result of the EUC, the trend factor (specific to the PC, TC, or both for an included cancer type) for the upcoming PY has increased or decreased by more than 10 percent compared to the corresponding trend factor of the previous CY when FFS payment rates are held constant with the previous CY, CMS may modify the trend factor calculation for the PC, TC, or both the PC and TC of an included cancer type in a manner that ensures the trend factor is consistent with the average utilization from the previous CY.

(f) ***Quality withhold.*** In response to a national, regional, or local event, CMS may adjust the quality withhold by choosing to repay the quality withhold during the next reconciliation and award all possible points in the subsequent AQS calculation amount or to not apply the quality withhold to RO Model payments during the EUC if CMS removes the quality measure and clinical data element reporting requirements pursuant to paragraph (c)(1) of this section.

[86 FR 63997, Nov. 16, 2021]

Subpart C—ESRD Treatment Choices Model

GENERAL

§ 512.300 Basis and scope.

(a) ***Basis.*** This subpart implements the test of the End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model under section 1115A(b) of the Act. Except as specifically noted in this subpart, the regulations under this subpart must not be construed to affect the applicability of other provisions affecting providers and suppliers under Medicare FFS, including the applicability of provisions regarding payment, coverage, or program integrity.

(b) ***Scope.*** This subpart sets forth the following:

(1) The duration of the ETC Model.

(2) The method for selecting ETC Participants.

(3) The schedule and methodologies for the Home Dialysis Payment Adjustment and Performance Payment Adjustment.

(4) The methodology for ETC Participant performance assessment for purposes of the Performance Payment Adjustment, including beneficiary attribution, benchmarking and scoring, and calculating the Modality Performance Score.

(5) Monitoring and evaluation, including quality measure reporting.

(6) Medicare payment waivers.

§ 512.310 Definitions.

For purposes of this subpart, the following definitions apply.

Adjusted ESRD PPS per Treatment Base Rate means the per treatment payment amount as defined in § 413.230 of this chapter, including patient-level adjustments and facility-level adjustments, and excluding any applicable training adjustment, add-on payment amount, outlier payment amount, transitional drug add-on payment adjustment (TDAPA) amount, and transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) amount.

Benchmark Year (BY) means the 12-month period that begins 18 months prior to the start of a given measurement year (MY) from which data are used to construct benchmarks against which to score an ETC Participant's achievement and improvement on the home dialysis rate and transplant rate for the purpose of calculating the ETC Participant's MPS.

Clinical staff means a licensed social worker or registered dietician/nutrition professional who furnishes services for which payment may be made under the physician fee schedule under the direction of and incident to the services of the Managing Clinician who is an ETC Participant.

Clinician Home Dialysis Payment Adjustment (Clinician HDPA) means the payment adjustment to the MCP for a Managing Clinician who is an ETC Participant, for the Managing Clinician's home dialysis claims, as described in §§ 512.345 and 512.350.

Clinician Performance Payment Adjustment (Clinician PPA) means the payment adjustment to the MCP for a Managing Clinician who is an ETC Participant based on the Managing Clinician's MPS, as described in §§ 512.375(b) and 512.380.

Comparison Geographic Area(s) means those HRRs that are not Selected Geographic Areas.

ESRD Beneficiary means a beneficiary who meets any of the following:

(1) Is receiving dialysis or other services for end-stage renal disease, up to and including the month in which the beneficiary receives a kidney transplant up to and including the month in which the beneficiary receives a kidney transplant.

(2) Has already received a kidney transplant and has a non-AKI dialysis or MCP claim at least 12 months after the beneficiary's latest transplant date.

(3) Has a kidney transplant failure less than 12 months after the beneficiary's latest transplant date as identified by:

(i) Two or more MCP claims in the180 days following the date on which the kidney transplant was received;

(ii) 24 or more maintenance dialysis treatments at any time after 180 days following the transplant date; or,

(iii) Indication of a transplant failure after the beneficiary's date of transplant based on data from the Scientific Registry of Transplant Recipients (SRTR) database.

(4) If a beneficiary meets more than one of criteria described in paragraphs (3)(i) through (iii) of this definition, the beneficiary will be considered an ESRD beneficiary starting with the earliest month in which transplant failure was recorded.

ESRD facility means an ESRD facility as specified in § 413.171 of this chapter.

ETC Participant means an ESRD facility or Managing Clinician that is required to participate in the ETC Model pursuant to § 512.325(a).

Facility Home Dialysis Payment Adjustment (Facility HDPA) means the payment adjustment to the Adjusted ESRD PPS per Treatment Base Rate for an ESRD facility that is an ETC Participant for the ESRD facility's home dialysis claims, as described in §§ 512.340 and 512.350.

Facility Performance Payment Adjustment (Facility PPA) means the payment adjustment to the Adjusted ESRD PPS per treatment base rate for an ESRD facility that is an ETC Participant based on the ESRD facility's MPS, as described in §§ 512.375(a) and 512.380.

Health Equity Incentive means the amount added to the ETC Participant's improvement score, calculated as described in § 512.370(c)(1), if the ETC Participant's aggregation group demonstrated sufficient improvement on the home dialysis rate or transplant rate for attributed beneficiaries who are dual eligible or Medicare Low Income Subsidy (LIS) recipients between the Benchmark Year and the MY.

Home Dialysis Payment Adjustment (HDPA) means either the Facility HDPA or the Clinician HDPA.

Home dialysis rate means the rate of ESRD Beneficiaries attributed to the ETC Participant who dialyzed at home during the relevant MY, as described in § 512.365(b).

Hospital referral regions (HRRs) means the regional markets for tertiary medical care derived from Medicare claims data as defined by the Dartmouth Atlas Project at *https://www.dartmouthatlas.org/*.

Kidney transplant means a kidney transplant, alone or in conjunction with any other organ.

Living donor transplant (LDT) Beneficiary means an ESRD Beneficiary who received a kidney transplant from a living donor.

Living donor transplant rate means the rate of ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries attributed to the ETC Participant who received a kidney transplant from a living donor during the MY, as described in § 512.365(c)(1)(ii) and § 512.365(c)(2)(ii).

Managing Clinician means a Medicare-enrolled physician or non-physician practitioner, identified by a National Provider Identifier (NPI), who furnishes and bills the MCP for managing one or more adult ESRD Beneficiaries.

Measurement Year (MY) means the 12-month period for which achievement and improvement on the home dialysis rate and transplant rate are assessed for the purpose of calculating the ETC Participant's MPS and corresponding PPA. Each MY included in the ETC Model and its corresponding PPA Period are specified in § 512.355(c).

Modality Performance Score (MPS) means the numeric performance score calculated for each ETC Participant based on the ETC Participant's home dialysis rate and transplant rate, as described in § 512.370(a), which is used to determine the amount of the ETC Participant's PPA, as described in § 512.380.

Monthly capitation payment (MCP) means the monthly capitated payment made for each ESRD Beneficiary to cover all routine professional services related to treatment of the patient's renal condition furnished by the physician or non-physician practitioner as specified in § 414.314 of this chapter.

National Provider Identifier (NPI) means the standard unique health identifier used by health care providers for billing payors, assigned by the National Plan and Provider Enumeration System (NPPES) in 45 CFR part 162.

Performance Payment Adjustment (PPA) means either the Facility PPA or the Clinician PPA.

Performance Payment Adjustment Period (PPA Period) means the six-month period during which a PPA is applied in accordance with § 512.380.

Pre-emptive LDT Beneficiary means a beneficiary who received a kidney transplant from a living donor prior to beginning dialysis.

Qualified staff means both clinical staff and any qualified person (as defined at § 410.48(a) of this chapter) who is an ETC Participant.

Selected Geographic Area(s) are those HRRs selected by CMS pursuant to § 512.325(b) for purposes of selecting ESRD facilities and Managing Clinicians required to participate in the ETC Model as ETC Participants.

Subsidiary ESRD facility is an ESRD facility owned in whole or in part by another legal entity.

Taxpayer Identification Number (TIN) means a Federal taxpayer identification number or employer identification number as defined by the Internal Revenue Service in 26 CFR 301.6109-1.

Transplant rate means the sum of the transplant waitlist rate and the living donor transplant rate, as described in § 512.365(c).

Transplant waitlist rate means the rate of ESRD Beneficiaries attributed to the ETC Participant who were on the kidney transplant waitlist during the MY, as described in § 512.365(c)(1)(i)-(ii) and § 512.365(c)(2)(i)-(ii).

[85 FR 61362, Sept. 29, 2020, as amended at 86 FR 62020, Nov. 8, 2021; 89 FR 89213, Nov. 12, 2024]

ESRD Treatment Choices Model Scope and Participants

§ 512.320 Duration.

CMS will apply the payment adjustments described in this subpart under the ETC Model to claims with claim service dates beginning on or after January 1, 2021, and ending on or before December 31, 2025.

[90 FR 53139, Nov. 24, 2025]

§ 512.325 Participant selection and geographic areas.

(a) ***Selected participants.*** All Medicare-certified ESRD facilities and Medicare-enrolled Managing Clinicians located in a selected geographic area are required to participate in the ETC Model.

(b) ***Selected Geographic Areas.*** CMS establishes the Selected Geographic Areas by selecting all HRRs for which at least 20 percent of the component zip codes are located in Maryland, and a random sample of 30 percent of HRRs, stratified by Census-defined regions (Northeast, South, Midwest, and West). CMS excludes all U.S. Territories from the Selected Geographic Areas.

§ 512.330 Beneficiary notification.

(a) ***General.*** ETC Participants must prominently display informational materials in each of their office or facility locations where beneficiaries receive treatment to notify beneficiaries that the ETC Participant is participating in the ETC Model. CMS provides the ETC Participant with a template for these materials, indicating the required content that the ETC Participant must not change and places where the ETC Participant may insert its own original content. The CMS-provided template for the beneficiary notification will include, without limitation, the following information:

(1) A notification that the ETC Participant is participating in the ETC Model;

(2) Instructions on how to contact the ESRD Network Organizations with any questions or concerns about the ETC Participant's participation in the Model;

(3) An affirmation of the ESRD Beneficiary's protections under Medicare, including the beneficiary's freedom to choose his or her provider or supplier and to select the treatment modality of his or her choice.

(b) ***Applicability of general Innovation Center model provisions.*** The requirement described in § 512.120(c)(2) shall not apply to the CMS-provided materials described in paragraph (a) of this section. All other ETC Participant communications that are descriptive model materials and activities as defined under § 512.110 must meet the requirements described in § 512.120(c).

Home Dialysis Payment Adjustment

§ 512.340 Payments subject to the Facility HDPA.

CMS adjusts the Adjusted ESRD PPS per Treatment Base Rate by the Facility HDPA on claim lines with Type of Bill 072X, and with condition codes 74 or 76, when the claim is submitted by an ESRD facility that is an ETC Participant with a claim service date during a calendar year subject to adjustment as described in § 512.350 and the beneficiary is at least 18 years old before the first day of the month.

§ 512.345 Payments subject to the Clinician HDPA.

CMS adjusts the amount otherwise paid under Medicare Part B with respect to MCP claims on claim lines with CPT codes 90965 and 90966 by the Clinician HDPA when the claim is submitted by a Managing Clinician who is an ETC Participant with a claim service date during a calendar year subject to adjustment as described in § 512.350 and the beneficiary is at least 18 years old before the first day of the month.

§ 512.350 Schedule of home dialysis payment adjustments.

CMS adjusts the payments specified in § 512.340 by the Facility HDPA and adjusts the payments specified in § 512.345 by the Clinician HDPA, according to the following schedule:

(a) Calendar year 2021: +3 percent.

(b) Calendar year 2022: +2 percent.

(c) Calendar year 2023: +1 percent.

PERFORMANCE PAYMENT ADJUSTMENT

§ 512.355 Schedule of performance assessment and performance payment adjustment.

(a) ***Measurement Years.*** CMS assesses ETC Participant performance on the home dialysis rate and the transplant rate during each of the MYs. The first MY begins on January 1, 2021, and the final MY ends on December 31, 2024.

(b) ***Performance Payment Adjustment Period.*** CMS adjusts payments for ETC Participants by the PPA during each of the PPA Periods, each of which corresponds to a MY. The first PPA Period begins on July 1, 2022, and the final PPA Period ends on December 31, 2025.

(c) ***Measurement Years and Performance Payment Adjustment Periods.*** MYs and PPA Periods follow the following schedule:

TABLE 1 TO PARAGRAPH (c)—ETC MODEL SCHEDULE OF MEASUREMENT YEARS AND PPA PERIODS

Measurement Year (MY)	Performance Payment Adjustment (PPA) period
MY 1—1/1/2021 through 12/31/2021	PPA Period 1—7/1/2022 through 12/31/2022.
MY 2—7/1/2021 through 6/30/2022	PPA Period 2—1/1/2023 through 6/30/2023.
MY 3—1/12022 through 12/31/2022	PPA Period 3—7/1/2023 through 12/31/2023.
MY 4—7/1/2022 through 6/30/2023	PPA Period 4—1/1/2024 through 6/30/2024.
MY 5—1/1/2023 through 12/31/2023	PPA Period 5—7/1/2024 through 12/31/2024.
MY 6—7/1/2023 through 6/30/2024	PPA Period 6—1/1/2025 through 6/30/2025.
MY 7—1/1/2024 through 12/31/2024	PPA Period 7—7/1/2025 through 12/31/2025.

[85 FR 61362, Sept. 29, 2020, as amended at 90 FR 53139, Nov. 24, 2025]

§ 512.360 Beneficiary population and attribution.

(a) ***General.*** Except as provided in paragraph (b) of this section, CMS attributes ESRD Beneficiaries to an ETC Participant for each month during a MY based on the ESRD Beneficiary's receipt of services specified in paragraph (c) of this section during that month, for the purpose of assessing the ETC Participant's performance on the home dialysis rate and transplant rate during that MY. Except as provided in paragraph (b) of this section, CMS attributes Pre-emptive LDT Beneficiaries to a Managing Clinician for one or more months during a MY based on the Pre-emptive LDT Beneficiary's receipt of services specified in paragraph (c)(2) of this section during that MY, for the purpose of assessing the Managing Clinician's performance on the living donor transplant rate during that MY. CMS attributes ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries to the ETC Participant for each month during a MY

retrospectively after the end of the MY. CMS attributes an ESRD Beneficiary to no more than one ESRD facility and no more than one Managing Clinician for a given month during a given MY. CMS attributes a Pre-emptive LDT Beneficiary to no more than one Managing Clinician for a given MY.

(b) ***Exclusions from attribution.*** CMS does not attribute an ESRD Beneficiary or Pre-emptive LDT Beneficiary to an ETC Participant for a month if, at any point during the month, the beneficiary—

(1) Is not enrolled in Medicare Part B;

(2) Is enrolled in Medicare Advantage, a cost plan, or other Medicare managed care plan;

(3) Does not reside in the United States;

(4) Is younger than 18 years of age before the first day of the month of the claim service date;

(5) Has elected hospice;

(6) Is receiving dialysis only for any acute kidney injury (AKI);

(7) Has a diagnosis of dementia at any point during the month of the claim service date or the preceding 12 months, as identified using the most recent dementia-related criteria at the time of beneficiary attribution, using the CMS-HCC (Hierarchical Condition Category) Risk Adjustment Model ICD-10-CM Mappings; or

(8) Is residing in or receiving dialysis in a skilled nursing facility (SNF) or nursing facility.

(c) ***Attribution services*** —

(1) ***ESRD facility beneficiary attribution.*** To be attributed to an ESRD facility that is an ETC Participant for a month, an ESRD Beneficiary must not be excluded based on the criteria specified in paragraph (b) of this section and must have received renal dialysis services during the month from the ESRD facility. CMS does not attribute Pre-emptive LDT Beneficiaries to ESRD facilities.

(i) An ESRD Beneficiary is attributed to the ESRD facility at which the ESRD Beneficiary received the plurality of his or her dialysis treatments in that month, other than renal dialysis services for AKI, as identified by claims with Type of Bill 072X, with claim service dates at the claim header through date during the month.

(ii) If the ESRD Beneficiary receives an equal number of dialysis treatments from two or more ESRD facilities in a given month, CMS attributes the ESRD Beneficiary to the ESRD facility at which the beneficiary received the earliest dialysis treatment that month. If the ESRD Beneficiary receives an equal number of dialysis treatments from two or more ESRD facilities in a given month and the ESRD beneficiary received the earliest dialysis treatment that month from more than one ESRD facility, CMS attributes the beneficiary to one of the ESRD facilities that furnished the earliest dialysis treatment that month at random.

(2) ***Managing Clinician beneficiary attribution.***

(i) An ESRD beneficiary who is not excluded based on the criteria in paragraph (b) of this section is attributed to a Managing Clinician who is an ETC Participant for a month if that Managing Clinician submitted an MCP claim for services furnished to the beneficiary, identified with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966, with claim service dates at the claim line through date during the month.

(A) If more than one Managing Clinician submits a claim for the MCP furnished to a single ESRD Beneficiary with a claim service date at the claim line during the month, the ESRD Beneficiary is attributed to the Managing Clinician associated with the earliest claim service date at the claim line through date during the month.

(B) If more than one Managing Clinician submits a claim for the MCP furnished to a single ESRD Beneficiary with the same earliest claim service date at the claim line through date for the month, the ESRD Beneficiary is randomly attributed to one of these Managing Clinicians.

(ii) For MY1 and MY2, a Pre-emptive LDT Beneficiary who is not excluded based on the criteria in paragraph (b) of this section is attributed to the Managing Clinician with whom the beneficiary has had the most claims between the start of the MY and the month in which the beneficiary received the transplant for all months between the start of the MY and the month of the transplant.

(A) If no Managing Clinician has had the plurality of claims for a given Pre-emptive LDT Beneficiary such that multiple Managing Clinicians each had the same number of claims for that beneficiary during the MY, the Pre-emptive LDT Beneficiary is attributed to the Managing Clinician associated with the latest claim service date at the claim line through date during the MY up to and including the month of the transplant.

(B) If no Managing Clinician had the plurality of claims for a given Pre-emptive LDT Beneficiary such that multiple Managing Clinicians each had the same number of services for that beneficiary during the MY, and more than one of those Managing Clinicians had the latest claim service date at the claim line through date during the MY up to and including the month of the transplant, the Pre-emptive LDT Beneficiary is randomly attributed to one of these Managing Clinicians.

(iii) For MY3 through MY7, a Pre-emptive LDT Beneficiary who is not excluded based on the criteria in paragraph (b) of this section is attributed to the Managing Clinician who submitted the most claims for services furnished to the beneficiary in the 365 days preceding the date in which the beneficiary received the transplant.

(A) If no Managing Clinician has had the most claims for a given Pre-emptive LDT Beneficiary such that multiple Managing Clinicians each had the same number of claims for that beneficiary in the 365 days preceding the date of the transplant, the Pre-emptive LDT Beneficiary is attributed to the Managing Clinician associated with the latest claim service date at the claim line through date during the 365 days preceding the date of the transplant.

(B) If no Managing Clinician had the most claims for a given Pre-emptive LDT Beneficiary such that multiple Managing Clinicians each had the same number of claims for that beneficiary in the 365 days preceding the date of the transplant, and more than one of those Managing Clinicians had the latest claim service date at the claim line through date during the 365 days preceding the date of the transplant, the Pre-emptive LDT Beneficiary is randomly attributed to one of these Managing Clinicians.

(C) The Pre-emptive LDT Beneficiary is considered eligible for attribution under this paragraph (c)(2)(iii) if the Pre-emptive LDT Beneficiary has at least 1-eligible month during the 12-month period that includes the month of the transplant and the 11 months prior to the month of the transplant. An eligible month refers to a month during which the Pre-emptive LDT Beneficiary not does not meet exclusion criteria in paragraph (b) of this section.

[85 FR 61362, Sept. 29, 2020, as amended at 86 FR 62021, Nov. 8, 2021; 90 FR 53139, Nov. 24, 2025]

§ 512.365 Performance assessment.

(a) ***General.*** For each MY, CMS separately assesses the home dialysis rate and the transplant rate for each ETC Participant based on the population of ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries attributed to the ETC Participant under § 512.360. Information used to calculate the home dialysis rate and the transplant rate includes Medicare claims data, Medicare administrative data, and data from the Scientific Registry of Transplant Recipients.

(b) ***Home dialysis rate.*** CMS calculates the home dialysis rate for ESRD facilities and Managing Clinicians as follows.

(1) ***Home dialysis rate for ESRD facilities.***

(i) The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that one beneficiary year is composed of 12 beneficiary months. Months during which attributed ESRD Beneficiaries received maintenance dialysis are identified by claims with Type of Bill 072X.

(ii) For MY3 through MY7, the numerator is the total number of home dialysis treatment beneficiary years, plus one half the total number of self dialysis treatment beneficiary years, plus one half the total number of nocturnal in center dialysis beneficiary years for attributed ESRD Beneficiaries during the MY.

(A) Home dialysis treatment beneficiary years included in the numerator are composed of those months during which attributed ESRD Beneficiaries received maintenance dialysis at home, such that 1-beneficiary year is comprised of 12-beneficiary months. Months in which an attributed ESRD Beneficiary received maintenance dialysis at home are identified by claims with Type of Bill 072X and condition codes 74 or 76.

(B) Self dialysis treatment beneficiary years included in the numerator are composed of those months during which attributed ESRD Beneficiaries received self dialysis in center, such that 1-beneficiary year is comprised of 12-beneficiary months. Months in which an attributed ESRD Beneficiary received self dialysis are identified by claims with Type of Bill 072X and condition code 72.

(C) Nocturnal in center dialysis beneficiary years included in the numerator are composed of those months during which attributed ESRD Beneficiaries received nocturnal in center dialysis, such that 1-beneficiary year is comprised of 12-beneficiary months. Months in which an attributed ESRD Beneficiary received nocturnal in center dialysis are identified by claims with Type of Bill 072X and modifier UJ.

(iii) Information used to calculate the ESRD facility home dialysis rate includes Medicare claims data and Medicare administrative data.

(iv) The ESRD facility home dialysis rate is aggregated, as described in paragraph (e)(1) of this section.

(2) ***Home dialysis rate for Managing Clinicians.***

(i) The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that one beneficiary year is comprised of 12 beneficiary months. Months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966.

(ii) For MY3 through MY7, the numerator is the total number of home dialysis treatment beneficiary years, plus one half the total number of self dialysis treatment beneficiary years, plus one half the total number of nocturnal in center dialysis beneficiary years for attributed ESRD Beneficiaries during the MY.

(A) Home dialysis treatment beneficiary years included in the numerator are composed of those months during which attributed ESRD Beneficiaries received maintenance dialysis at home, such that 1-beneficiary year is comprised of 12-beneficiary months. Months in which an attributed ESRD Beneficiary received maintenance dialysis at home are identified by claims with CPT codes 90965 or 90966.

(B) Self-dialysis treatment beneficiary years included in the numerator are composed of those months during which attributed ESRD Beneficiaries received self dialysis in center, such that 1-beneficiary year is comprised of 12-beneficiary months. Months in which an attributed ESRD Beneficiary received self dialysis are identified by claims with Type of Bill 072X and condition code 72.

(C) Nocturnal in center dialysis beneficiary years included in the numerator are composed of those months during which attributed ESRD Beneficiaries received nocturnal in center dialysis, such that 1-beneficiary year is comprised of 12-beneficiary months. Months in which an attributed ESRD Beneficiary received nocturnal in center dialysis are identified by claims with Type of Bill 072X and modifier UJ.

(iii) Information used to calculate the Managing Clinician home dialysis rate includes Medicare claims data and Medicare administrative data.

(iv) The Managing Clinician home dialysis rate is aggregated, as described in paragraph (e)(2) of this section.

(c) ***Transplant rate.*** CMS calculates the transplant rate for ETC Participants as follows.

(1) ***Transplant rate for ESRD facilities.*** The transplant rate for ESRD facilities is the sum of the transplant waitlist rate for ESRD facilities, as described in paragraph (c)(1)(i) of this section, and the living donor transplant rate for ESRD facilities, as described in paragraph (c)(1)(ii) of this section.

(i) ***Transplant waitlist rate for ESRD facilities.***

(A) The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD beneficiary received maintenance dialysis at home or in an ESRD facility, such that 1-beneficiary year is comprised of 12-beneficiary months. For MY3 through MY7, months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with Type of Bill 072X, excluding claims for beneficiaries who were 75 years of age or older at any point during the month, or had a vital solid organ cancer diagnosis and were receiving treatment with chemotherapy or radiation for vital solid organ cancer during the MY.

(*1*) An attributed ESRD Beneficiary had a diagnosis of vital solid organ cancer in an MY if the beneficiary had any of the following diagnosis codes on any claim during the MY or the 6 months prior to the start of the MY: C22.0, C22.1, C22.2, C22.3, C22.4, C22.7, C22.8, C22.9, C34.10-C34.12, C34.2, C34.30-C34.32, C34.80-C34.82, C34.90-C34.92, C38.0, C38.8, C46.50-C46.52, C64.1, C64.2, C64.2, C78.00-C78.02, C78.7, C79.00-C79.02, C7A.090, C7A.093, or C7B.02.

(*2*) An attributed ESRD Beneficiary received treatment with chemotherapy or radiation for vital solid organ cancer during the MY if the beneficiary had a claim with any of the following procedure codes on any claim during the MY or the 6 months prior to the start of the MY:

(*i*) CPT® 96401-96402, 96405-96406, 96409, 96411, 96413, 96415-96417, 96420, 96422-26423, 96425, 96440, 96446, 96549, 77373, 77401-77402, 77407, 77412, 77423, 77424-77425, 77520, 77522-77523, 77525, 77761-77763, 77770-77772, 77778, 77789, 77799, 79005, 79101, 79200, 79300, 79403, 79440, 79445, 79999.

(*ii*) ICD-10-PCS® DB020ZZ, DB021ZZ, DB022ZZ, DB023Z0, DB023ZZ, DB024ZZ, DB025ZZ, DB026ZZ, DB1297Z, DB1298Z, DB1299Z, DB129BZ, DB129CZ, DB129YZ, DB12B6Z, DB12B7Z, DB12B8Z, DB12B9Z, DB12BB1, DB12BBZ, DB12BCZ, DB12BYZ, DB22DZZ, DB22HZZ, DB22JZZ, DBY27ZZ, DBY28ZZ, DBY2FZZ, DBY2KZZ, DB070ZZ, DB071ZZ, DB072ZZ, DB073Z0, DB073ZZ, DB074ZZ, DB075ZZ, DB076ZZ, DB1797Z, DB1798Z, DB1799Z, DB179BZ, DB179CZ, DB179YZ, DB17B6Z, DB17B7Z, DB17B8Z, DB17B9Z, DB17BB1, DB17BBZ, DB17BCZ, DB17BYZ, DB27DZZ, DB27HZZ, DB27JZZ, DBY77ZZ, DBY78ZZ, DBY7FZZ, DBY7KZZ, DF000ZZ, DF001ZZ, DF002ZZ, DF003Z0, DF003ZZ, DF004ZZ, DF005ZZ, DF006ZZ, DF1097Z, DF1098Z, DF1099Z, DF109BZ, DF109CZ, DF109YZ, DF10B6Z, DF10B7Z, DF10B8Z, DF10B9Z, DF10BB1, DF10BBZ, DF10BCZ, DF10BYZ, DF20DZZ, DF20HZZ, DF20JZZ, DFY07ZZ, DFY08ZZ, DFY0CZZ, DFY0FZZ, DFY0KZZ, DT000ZZ, DT001ZZ, DT002ZZ, DT003Z0, DT003ZZ, DT004ZZ, DT005ZZ, DT006ZZ, DT1097Z, DT1098Z, DT1099Z, DT109BZ, DT109CZ, DT109YZ, DT10B6Z, DT10B7Z, DT10B8Z, DT10B9Z, DT10BB1, DT10BBZ, DT10BCZ, DT10BYZ, DT20DZZ, DT20HZZ, DT20JZZ, DTY07ZZ, DTY08ZZ, DTY0CZZ, DTY0FZZ, DW020ZZ, DW021ZZ, DW022ZZ, DW023Z0, DW023ZZ, DW024ZZ, DW025ZZ, DW026ZZ, DW1297Z, DW1298Z, DW1299Z, DW129BZ, DW129CZ, DW129YZ, DW12B6Z, DW12B7Z, DW12B8Z, DW12B9Z, DW12BB1, DW12BBZ, DW12BCZ, DW12BYZ, DW22DZZ, DW22HZZ, DW22JZZ, DWY27ZZ, DWY28ZZ, DWY2FZZ, DW030ZZ, DW031ZZ, DW032ZZ, DW033Z0, DW033ZZ, DW034ZZ, DW035ZZ, DW036ZZ,

DW1397Z, DW1398Z, DW1399Z, DW139BZ, DW139CZ, DW139YZ, DW13B6Z, DW13B7Z, DW13B8Z, DW13B9Z, DW13BB1, DW13BBZ, DW13BCZ, DB13BYZ, DW23DZZ, DW23HZZ, DW23JZZ, DWY37ZZ, DWY38ZZ, DWY3FZZ, DW050ZZ, DW051ZZ, DW052ZZ, DW053Z0, DW053ZZ, DW054ZZ, DW055ZZ, DW056ZZ, DWY57ZZ, DWY58ZZ, DWY5FZZ, DWY5GDZ, DWY5GFZ, DWY5GGZ, DWY5GHZ, DWY5GYZ.

(B) The numerator is the total number of attributed beneficiary years for which attributed ESRD Beneficiaries were on the kidney transplant waitlist. Months during which an attributed ESRD Beneficiary was on the kidney transplant waitlist are identified using data from the SRTR database.

(ii) ***Living donor transplant rate for ESRD facilities.***

(A) The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that 1-beneficiary year is comprised of 12-beneficiary months. For MY3 through MY7, months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with Type of Bill 072X, excluding claims for beneficiaries who were 75 years of age or older at any point during the month, or had a vital solid organ cancer diagnosis and were receiving treatment with chemotherapy or radiation for vital solid organ cancer during the MY. Months in which an attributed ESRD Beneficiary had a diagnosis of vital solid organ cancer are identified as described in paragraph (c)(1)(i)(A)(*1*) of this section. Months in which an attributed ESRD Beneficiary received treatment with chemotherapy or radiation for vital solid organ cancer are identified as described in paragraph (c)(1)(i)(A)(*2*) of this section.

(B) The numerator is the total number of attributed beneficiary years for LDT Beneficiaries during the MY. Beneficiary years for LDT Beneficiaries included in the numerator are composed of those months between the beginning of the MY up to and including the month of the transplant for LDT Beneficiaries attributed to an ESRD facility during the month of the transplant. LDT Beneficiaries are identified using information about living donor transplants from the SRTR Database and Medicare claims data.

(iii) The ESRD facility transplant waitlist rate is risk adjusted, as described in paragraph (d) of this section. The ESRD facility transplant rate is aggregated, as described in paragraph (e)(1) of this section.

(2) ***Transplant rate for Managing Clinicians.*** The transplant rate for Managing Clinicians is the sum of the transplant waitlist rate for Managing Clinicians, as described in paragraph (c)(2)(i) of this section, and the living donor transplant rate for Managing Clinicians, as described in paragraph (c)(2)(ii) of this section.

(i) ***Transplant waitlist rate for Managing Clinicians.***

(A) The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that 1-beneficiary year is comprised of 12-beneficiary months. For MY3 through MY7, months during which an

attributed ESRD Beneficiary received maintenance dialysis are identified by claims with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966, excluding claims for beneficiaries who were 75 years of age or older at any point during the month, or had a vital solid organ cancer diagnosis and were receiving treatment with chemotherapy or radiation for vital solid organ cancer during the MY. Months in which an attributed ESRD Beneficiary had a diagnosis of vital solid organ cancer are identified as described in paragraph (c)(1)(i)(A)(1) of this section. Months in which an attributed ESRD Beneficiary received treatment with chemotherapy or radiation for vital solid organ cancer are identified as described in paragraph (c)(1)(i)(A)(2) of this section.

(B) The numerator is the total number of attributed beneficiary years for which attributed ESRD Beneficiaries were on the kidney transplant waitlist. Months during which an attributed ESRD Beneficiary was on the kidney transplant waitlist are identified using data from the SRTR database.

(ii) ***Living donor transplant rate for Managing Clinicians.***

(A) The denominator is the sum of the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY and the total Pre-emptive LDT beneficiary years for attributed beneficiaries during the MY.

(*1*) Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that 1-beneficiary year is comprised of 12-beneficiary months. For MY3 through MY7, months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966, excluding claims for beneficiaries who were 75 years of age or older at any point during the month, or had a vital solid organ cancer diagnosis and were receiving treatment with chemotherapy or radiation for vital solid organ cancer during the MY. Months in which an attributed ESRD Beneficiary had a vital solid organ cancer diagnosis are identified as described in paragraph (c)(1)(i)(A)(*1*) of this section. Months in which an attributed ESRD Beneficiary received treatment with chemotherapy or radiation for vital solid organ cancer are identified as described in paragraph (c)(1)(i)(A)(*2*) of this section.

(*2*) MY1 and MY2, Pre-emptive LDT beneficiary years included in the denominator are composed of those months during which a Pre-emptive LDT Beneficiary is attributed to a Managing Clinician, from the beginning of the MY up to and including the month of the living donor transplant. For MY3 through MY7, Pre-emptive LDT beneficiary years included in the denominator are composed of those months during which a Pre-emptive LDT Beneficiary is attributed to a Managing Clinician, from the beginning of the MY up to and including the month of the living donor transplant, excluding beneficiaries who had a vital solid organ cancer diagnosis and were receiving treatment with chemotherapy or radiation for vital solid organ cancer during the MY. Months in which an attributed ESRD Beneficiary had a vital solid organ cancer diagnosis are identified as described in paragraph (c)(1)(i)(A)(1) of this section. Months in which an attributed ESRD Beneficiary received treatment with chemotherapy or radiation for vital solid organ cancer are identified as described in

paragraph (c)(1)(i)(A)(2) of this section. Pre-emptive LDT Beneficiaries are identified using information about living donor transplants from the SRTR Database and Medicare claims data.

(B) The numerator is the sum of the total number of attributed beneficiary years for LDT Beneficiaries during the MY and the total number of attributed beneficiary years for Pre-emptive LDT Beneficiaries during the MY.

(*1*) Beneficiary years for LDT Beneficiaries included in the numerator are composed of those months during which an LDT Beneficiary is attributed to a Managing Clinician, from the beginning of the MY up to and including the month of the transplant. LDT Beneficiaries are identified using information about living donor transplants from the SRTR Database and Medicare claims data.

(*2*) Beneficiary years for Pre-emptive LDT Beneficiaries included in the numerator are composed of those months during which a Pre-emptive LDT Beneficiary is attributed to a Managing Clinician, from the beginning of the MY up to and including the month of the transplant. Pre-emptive LDT Beneficiaries are identified using information about living donor transplants from the SRTR Database and Medicare claims data.

(iii) The Managing Clinician transplant waitlist rate is risk adjusted, as described in paragraph (d) of this section. The Managing Clinician transplant rate is aggregated, as described in paragraph (e)(2) of this section.

(d) ***Risk adjustment.***

(1) CMS risk adjusts the transplant waitlist rate based on beneficiary age with separate risk coefficients for the following age categories of beneficiaries, with age computed on the last day of each month of the MY:

(i) 18 to 55.

(ii) 56 to 70.

(iii) 71 to 74.

(2) CMS risk adjusts the transplant waitlist rate to account for the relative percentage of the population of beneficiaries attributed to the ETC Participant in each age category relative to the national age distribution of beneficiaries not excluded from attribution.

(e) ***Aggregation*** —

(1) ***Aggregation for ESRD facilities.*** An ESRD facility's home dialysis rate and transplant rate are aggregated to the ESRD facility's aggregation group. The aggregation group for a Subsidiary ESRD facility includes all ESRD facilities owned in whole or in part by the same legal entity located in the HRR in which the ESRD facility is located. An ESRD facility that is not a Subsidiary ESRD facility is not included in an aggregation group.

(2) ***Aggregation for Managing Clinicians.*** A Managing Clinician's home dialysis rate and transplant rate are aggregated to the Managing Clinician's aggregation group. The aggregation group for a Managing Clinician who is—

(i) In a group practice is the practice group level, as identified by practice TIN; or

(ii) A solo practitioner is the individual clinician level, as identified by NPI.

[85 FR 61362, Sept. 29, 2020, as amended at 86 FR 62021, Nov. 8, 2021; 90 FR 53140, Nov. 24, 2025]

§ 512.370 Benchmarking and scoring.

(a) ***General.***

(1) CMS assesses the home dialysis rate and transplant rate for each ETC Participant against the applicable benchmarks to calculate an—

(i) Achievement score, as described in paragraph (b) of this section; and

(ii) Improvement score, as described in paragraph (c) of this section.

(2)

(i) CMS calculates the ETC Participant's MPS as the weighted sum of the higher of the achievement score or the improvement score for the ETC Participant's home dialysis rate and transplant rate, as described in paragraph (d) of this section.

(ii) The ETC Participant's MPS determines the ETC Participant's PPA, as described in § 512.380.

(b) ***Achievement Scoring.*** CMS assesses ETC Participant performance at the aggregation group level on the home dialysis rate and transplant rate against achievement benchmarks constructed based on the home dialysis rate and transplant rate among aggregation groups of ESRD facilities and Managing Clinicians located in Comparison Geographic Areas during the Benchmark Year. Achievement benchmarks are calculated as described in paragraph (b)(1) of this section and, for MY3 through MY7, are stratified as described in paragraph (b)(2) of this section. For MY5 through MY7, the ETC Participant's achievement score is subject to the restriction described in paragraph (b)(3) of this section.

(1) ***Achievement benchmarks.*** CMS uses the following scoring methodology to assess an ETC Participant's achievement score.

TABLE 1 TO § 512.370(b)(1)—ETC MODEL SCHEDULE OF PPA ACHIEVEMENT BENCHMARKS BY MEASUREMENT YEAR

MY1 and MY2	MY3 and MY4	MY5 and MY6	MY7	Points
90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year	1.1 * (90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.2 * (90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.3 * (90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	2
75th+ Percentile of benchmark rates for Comparison Geographic Areas during the	1.1 * (75th+ Percentile of benchmark rates for Comparison Geographic Areas	1.2 * (75th+ Percentile of benchmark rates for Comparison Geographic Areas	1.3 * (75th+ Percentile of benchmark rates for Comparison Geographic Areas	1.5

MY1 and MY2	MY3 and MY4	MY5 and MY6	MY7	Points
Benchmark Year	during the Benchmark Year)	during the Benchmark Year)	during the Benchmark Year)	
50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year	1.1 * (50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.2 * (50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.3 * (50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1
30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year	1.1 * (30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.2 * (30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.3 * (30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	0.5
<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year	1.1 * (<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.2 * (<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.3 * (<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	0

(2) ***Stratifying achievement benchmarks.*** For MY3 through MY7, CMS stratifies achievement benchmarks based on the proportion of beneficiary years attributed to the aggregation group for which attributed beneficiaries are dual eligible or LIS recipients during the MY. An ESRD Beneficiary or Pre-emptive LDT Beneficiary is considered to be dual eligible or a LIS recipient for a given month if at any point during the month the beneficiary was dual eligible or an LIS recipient based on Medicare administrative data. CMS stratifies the achievement benchmarks into the following two strata:

(i) ***Stratum 1:*** 50 percent or more of attributed beneficiary years during the MY are for beneficiaries who are dual eligible or LIS recipients.

(ii) ***Stratum 2:*** Less than 50 percent of attributed beneficiary years during the MY are for beneficiaries who are dual eligible or LIS recipients.

(3) For MY5 through MY7, CMS will assign an achievement score to an ETC Participant for the home dialysis rate or the transplant rate only if the ETC Participant's aggregation group has a home dialysis rate or a transplant rate greater than zero for the MY.

(c) ***Improvement scoring.*** CMS assesses ETC Participant improvement on the home dialysis rate and transplant rate against benchmarks constructed based on the ETC Participant's aggregation group's historical performance on the home dialysis rate and transplant rate during the Benchmark Year to calculate the ETC Participant's improvement score, as specified in paragraph (c)(1) of this section. For

MY3 through MY7, CMS assesses ETC Participant improvement on the home dialysis rate and transplant rate for ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries, who are dual eligible or LIS recipients to determine whether to add the Health Equity Incentive to the ETC Participant's improvement score, as specified in paragraph (c)(2) of this section.

(1) ***Improvement score calculation.*** CMS uses the following scoring methodology to assess an ETC Participant's improvement score.

(i) Greater than 10 percent improvement relative to the Benchmark Year rate: 1.5 points

(ii) Greater than 5 percent improvement relative to the Benchmark Year rate: 1 point

(iii) Greater than 0 percent improvement relative to the Benchmark Year rate: 0.5 points

(iv) Less than or equal to the Benchmark Year rate: 0 points

(v) For MY3 through MY7, when calculating improvement benchmarks constructed based on the ETC Participant's aggregation group's historical performance on the home dialysis rate and transplant rate during the Benchmark Year, CMS adds one beneficiary month to the numerator of the home dialysis rate and adds one beneficiary month to the numerator of the transplant rate, such that the Benchmark Year rates cannot be equal to zero.

(2) ***Health Equity Incentive.*** CMS calculates the ETC Participant's aggregation group's home dialysis rate and transplant rate as specified in §§ 512.365(b) and 512.365(c), respectively, using only attributed beneficiary years comprised of months during the MY in which ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries, are dual eligible or LIS recipients. CMS also calculates the threshold for earning the Health Equity Incentive based on the ETC Participant's aggregation group's historical performance on the home dialysis rate and transplant rate during the Benchmark Year, using only attributed beneficiary years comprised of months during the Benchmark Year in which ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries, are dual eligible or LIS recipients. An ESRD Beneficiary or Pre-emptive LDT Beneficiary is considered to be dual eligible or a LIS recipient for a given month if at any point during the month the beneficiary was dual eligible or a LIS recipient. CMS determines whether a beneficiary was dual eligible or a LIS recipient based on Medicare administrative data.

(i) The ETC Participant earns the Health Equity Incentive for the home dialysis rate improvement score if the home dialysis rate for the MY, calculated as specified in this paragraph (c)(2), is at least 2.5-percentage points higher than the home dialysis rate for the Benchmark Year, calculated as specified in this paragraph (c)(2). If the ETC Participant earns the Health Equity Incentive for the home dialysis rate improvement score, CMS adds 0.5 points to the ETC Participant's home dialysis rate improvement score, calculated as specified in paragraph (c)(1) of this section, unless the ETC Participant is ineligible to receive the Home Equity Incentive as specified in paragraph (c)(2)(iii) of this section.

(ii) The ETC Participant earns the Health Equity Incentive for the transplant rate improvement score if the home dialysis rate for the MY, calculated as specified in this paragraph (c)(2), is at least 2.5-percentage points higher than the transplant rate for the Benchmark Year, calculated as specified in this paragraph (c)(2). If the ETC Participant earns the Health Equity Incentive for the transplant rate improvement score, CMS adds 0.5 points to the ETC Participant's transplant rate improvement score, calculated as specified in paragraph (c)(1) of this section, unless the ETC Participant is ineligible to receive the Home Equity Incentive as specified in paragraph (c)(2)(iii) of this section.

(iii) An ETC Participant in an aggregation group with fewer than 11-attributed beneficiary years comprised of months in which ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries, are dual eligible or LIS recipients, during either the Benchmark Year or the MY is ineligible to earn the Health Equity Incentive.

(d) ***Modality Performance Score.***

(1) For MY1 and MY2, CMS calculates the ETC Participant's MPS as the higher of ETC Participant's achievement score or improvement score for the home dialysis rate, together with the higher of the ETC Participant's achievement score or improvement score for the transplant rate, weighted such that the ETC Participant's score for the home dialysis rate constitutes $^{2}/_{3}$ of the MPS and the ETC Participant's score for the transplant rate constitutes $^{1}/_{3}$ of the MPS. CMS uses the following formula to calculate the ETC Participant's MPS for MY1 and MY2:

Modality Performance Score = 2 × (*Higher of the home dialysis achievement or improvement score*) + (*Higher of the transplant achievement or improvement score*)

(2) For MY3 through MY7, CMS calculates the ETC Participant's MPS as the higher of the ETC Participant's achievement score for the home dialysis rate or the sum of the ETC Participant's improvement score for the home dialysis rate calculated as specified in paragraph (c)(1) of this section and, if applicable, the Health Equity Incentive, calculated as described in paragraph (c)(2)(i) of this section, together with the higher of the ETC Participant's achievement score for the transplant rate or the sum of the ETC Participant's improvement score for the transplant rate calculated as specified in paragraph (c)(1) of this section and, if applicable, the Heath Equity Incentive, calculated as described in paragraph (c)(2)(ii) of this section, weighted such that the ETC Participant's score for the home dialysis rate constitutes $^{2}/_{3}$ of the MPS and the ETC Participant's score for the transplant rate constitutes $^{1}/_{3}$ of the MPS. CMS uses the following formula to calculate the ETC Participant's MPS for MY3 through MY7: *Modality Performance Score* = 2 × (*Higher of the home dialysis achievement or* (*home dialysis improvement score + Health Equity Bonus* †)) + (*Higher of the transplant achievement or* (*transplant improvement score + Health Equity Bonus*†))

† The Health Equity Incentive is applied to the home dialysis improvement score or transplant improvement score only if earned by the ETC Participant.

[85 FR 61362, Sept. 29, 2020, as amended at 86 FR 62023, Nov. 8, 2021; 87 FR 67302, Nov. 7, 2022; 90 FR 53141, Nov. 24, 2025]

§ 512.375 Payments subject to adjustment.

(a) ***Facility PPA.*** CMS adjusts the Adjusted ESRD PPS per Treatment Base Rate by the Facility PPA on claim lines with Type of Bill 072X, when the claim is submitted by an ETC Participant that is an ESRD facility and the beneficiary is at least 18 years old before the first day of the month, on claims with claim service dates during the applicable PPA Period as described in § 512.355(c).

(b) ***Clinician PPA.*** CMS adjusts the amount otherwise paid under Medicare Part B with respect to MCP claims on claim lines with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965 and 90966 by the Clinician PPA when the claim is submitted by an ETC Participant who is a Managing Clinician and the beneficiary is at least 18 years old before the first day of the month, on claims with claim service dates during the applicable PPA Period as described in § 512.355(c).

§ 512.380 PPA Amounts and schedules.

CMS adjusts the payments described in § 512.375 based on the ETC Participant's MPS calculated as described in § 512.370(d) according to the following amounts and schedules in Table 1 and Table 2 to § 512.380.

Table 1 to § 512.380—Facility PPA Amounts and Schedule

	MPS	Performance payment adjustment period			
		1 and 2 (%)	3 and 4 (%)	5 and 6 (%)	7 (%)
Facility Performance Payment Adjustment	≤6	+4.0	+5.0	+6.0	+7.0
	≤5	+2.0	+2.5	+3.0	+3.5
	≤3.5	0	0	0	0
	≤2	−2.5	−3.0	−3.5	−4.5
	≤.5	−5.0	−6.0	−7.0	−9.0

Table 2 to § 512.380—Clinician PPA Amounts and Schedule

	MPS	Performance payment adjustment period			
		1 and 2 (%)	3 and 4 (%)	5 and 6 (%)	7 (%)
Clinician Performance Payment Adjustment	≤6	+4.0	+5.0	+6.0	+7.0
	≤5	+2.0	+2.5	+3.0	+3.5
	≤3.5	0	0	0	0
	≤2	−2.5	−3.0	−3.5	−4.0
	≤.5	−5.0	−6.0	−7.0	−8.0

[85 FR 61362, Sept. 29, 2020, as amended at 90 FR 53142, Nov. 24, 2025]

§ 512.385 PPA exclusions.

(a) ***ESRD facilities.*** CMS excludes an aggregation group (as described in § 512.365(e)(1) of Subsidiary ESRD facilities with fewer than 11 attributed ESRD beneficiary years during an MY from the applicability of the Facility PPA for the corresponding PPA Period. CMS excludes ESRD facilities that are not Subsidiary ESRD facilities with fewer than 11 attributed ESRD beneficiary years during an MY from the applicability of the Facility PPA for the corresponding PPA Period.

(b) ***Managing Clinicians.*** CMS excludes an aggregation group (as described in § 512.365(e)(2)) of Managing Clinicians with fewer than 11 attributed ESRD beneficiary years during an MY from the applicability of the Clinician PPA for the corresponding PPA Period.

§ 512.390 Notification, data sharing, and targeted review.

(a) ***Notification.*** CMS will notify each ETC Participant, in a form and manner determined by CMS, of the ETC Participant's attributed beneficiaries, MPS, and PPA for a PPA Period no later than one month before the start of the applicable PPA Period.

(b) ***Data sharing with ETC Participants.*** CMS shares certain beneficiary-identifiable data as described in paragraph (b)(1) of this section and certain aggregate data as described in paragraph (b)(2) of this section with ETC Participants regarding their attributed beneficiaries and performance under the ETC Model. Data will not be shared after November 30, 2025.

(1) ***Beneficiary-identifiable data.*** CMS shares beneficiary-identifiable data with ETC Participants as follows:

(i) CMS will make available certain beneficiary-identifiable data for retrieval by ETC Participants no later than one month before the start of each PPA Period, in a form and manner specified by CMS. ETC Participants may retrieve this data at any point during the relevant PPA Period.

(ii) This beneficiary-identifiable data includes, when available, the following information for each PPA Period:

(A) The ETC Participant's attributed beneficiaries' names, Medicare Beneficiary Identifiers, dates of birth, dual eligible status, and LIS recipient status.

(B) Data regarding the ETC Participant's performance under the ETC Model, including, for each attributed beneficiary, as applicable: the number of months the beneficiary was attributed to the ETC Participant, home dialysis months, self-dialysis months, nocturnal in-center dialysis months, transplant waitlist months, and months following a living donor transplant.

(iii) CMS shares this beneficiary-identifiable data on the condition that the ETC Participants observe all relevant statutory and regulatory provisions regarding the appropriate use of data and the confidentiality and privacy of individually identifiable health information as would apply to a covered entity under the regulations found at 45 CFR parts 160 and 164 promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended, and comply with the terms of the data sharing agreement described in paragraph (b)(1)(iv) of this section.

(iv) If an ETC Participant wishes to retrieve the beneficiary-identifiable data specified in paragraph (b)(1)(ii) of this section, the ETC Participant must complete and submit, on at least an annual basis, a signed data sharing agreement, to be provided in a form and manner specified by CMS, under which the ETC Participant agrees:

(A) To comply with the requirements for use and disclosure of this beneficiary-identifiable data that are imposed on covered entities by the HIPAA regulations and the requirements of the ETC Model set forth in this part.

(B) To comply with additional privacy, security, breach notification, and data retention requirements specified by CMS in the data sharing agreement.

(C) To contractually bind each downstream recipient of the beneficiary-identifiable data that is a business associate of the ETC Participant to the same terms and conditions to which the ETC Participant is itself bound in its data sharing agreement with CMS as a condition of the business associate's receipt of the beneficiary-identifiable data retrieved by the ETC Participant under the ETC Model.

(D) That if the ETC Participant misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the data sharing agreement, CMS may deem the ETC Participant ineligible to retrieve beneficiary-identifiable data under paragraph (b)(1)(i) of this section for any amount of time, and the ETC Participant may be subject to additional sanctions and penalties available under the law.

(2) ***Aggregate data.*** CMS shares aggregate performance data with ETC Participants as follows:

(i) CMS will make available certain aggregate data for retrieval by the ETC Participant, in a form and manner to be specified by CMS, no later than one month before each PPA Period.

(ii) This aggregate data includes, when available, the following information for each PPA Period, de-identified in accordance with 45 CFR 164.514(b):

(A) The ETC Participant's performance scores on the home dialysis rate, transplant waitlist rate, living donor transplant rate, and the Health Equity Incentive.

(B) The ETC Participant's aggregation group's scores on the home dialysis rate, transplant waitlist rate, and living donor transplant rate, and the Health Equity Incentive.

(C) Information on how the ETC Participant's and ETC Participant's aggregation group's scores relate to the achievement benchmark and improvement benchmark.

(D) The ETC Participant's MPS and PPA for the corresponding PPA Period.

(c) ***Targeted review process.*** An ETC Participant may request a targeted review of the calculation of the MPS. Requests for targeted review are limited to the calculation of the MPS, and may not be submitted in regards to: The methodology used to determine the MPS; or the establishment of the home dialysis rate methodology, transplant rate methodology, achievement and improvement benchmarks and benchmarking methodology, or PPA amounts. The process for targeted reviews is as follows:

(1) An ETC Participant has 90 days (or a later date specified by CMS) to submit a request for a targeted review, which begins on the day CMS makes available the MPS.

(2) CMS will respond to each request for targeted review timely submitted and determine whether a targeted review is warranted.

(3) The ETC Participant may include additional information in support of the request for targeted review at the time the request is submitted. If CMS requests additional information from the ETC Participant, it must be provided and received within 30 days of the request. Non-responsiveness to the request for additional information may result in the closure of the targeted review request.

(4) If, upon completion of a targeted review, CMS finds that there was an error in the calculation of the ETC Participant's MPS such that an incorrect PPA has been applied during the PPA period, CMS shall notify the ETC Participant and must resolve any resulting discrepancy in payment that arises from the application of an incorrect PPA in a time and manner determined by CMS.

(d) ***Review of targeted review decisions.*** The Administrator may review a targeted review request when administrative review is requested by an ETC Participant within 15-calendar days of a targeted review request determination made by CMS.

(1) ***Administrative review.*** Within 45 days of the date of the ETC Participant's request for administrative review, the CMS Administrator may act as follows:

(i) Decline to review a targeted review request determination made by CMS;

(ii) Render a final decision based on the CMS Administrator's review of the targeted review request determination; or

(iii) Choose to take no action on the request for administrative review.

(2) ***Administrative review determinations.*** The targeted review determination made by the CMS Administrator is final if the CMS Administrator declines an ETC Participant's request for administrative review or if the CMS Administrator does not take any action on the ETC Participant's request for administrative review by the end of the 45-day period described in paragraph (d)(1) of this section. CMS-1782-F

[85 FR 61362, Sept. 29, 2020, as amended at 86 FR 62024, Nov. 8, 2021; 88 FR 76506, Nov. 6, 2023; 90 FR 53142, Nov. 24, 2025]

Quality Monitoring

§ 512.395 Quality measures.

CMS collects data on these two quality measures for ESRD facilities that are ETC Participants to monitor for changes in quality outcomes. CMS conducts data collection and measure calculation using claims data and other Medicare administrative data, including enrollment data:

(a) Standardized Mortality Ratio (SMR); NQF #0369.

(b) Standardized Hospitalization Ratio (SHR); NQF #1463.

Medicare Program Waivers

§ 512.397 ETC Model Medicare program waivers and additional flexibilities.

The following provisions are waived solely for purposes of testing the ETC Model.

(a)

(1) ***Medicare payment waivers.*** CMS waives the requirements of sections 1833(a), 1833(b), 1848(a)(1), 1881(b), and 1881(h)(1)(A) of the Act only to the extent necessary to make the payment adjustments under the ETC Model described in this subpart.

(2) ***Beneficiary cost sharing.*** The payment adjustments under the ETC Model described in this subpart do not affect the beneficiary cost-sharing amounts for Part B services furnished by ETC Participants under the ETC Model.

(b) CMS waives the following requirements of title XVIII of the Act solely for purposes of testing the ETC Model:

(1) CMS waives the requirement under section 1861(ggg)(2)(A)(i) of the Act and § 410.48(a) of this chapter that only doctors, physician assistants, nurse practitioners, and clinical nurse specialists can furnish kidney disease patient education services to allow kidney disease patient education services to be provided by clinical staff (as defined at § 512.310) under the direction of and incident to the services of the Managing Clinician who is an ETC Participant. The kidney disease patient education services may be furnished only by qualified staff (as defined at § 512.310). Beginning MY5, only clinical staff that are not leased from or otherwise provided by an ESRD facility or related entity may furnish kidney disease patient education services pursuant to the waiver described in this section.

(2) CMS waives the requirement that kidney disease patient education services are covered only for Stage IV chronic kidney disease (CKD) patients under section 1861(ggg)(1)(A) of the Act and § 410.48(b)(1) of this chapter to permit beneficiaries diagnosed with CKD Stage V or within the first 6 months of starting dialysis to receive kidney disease patient education services.

(3) CMS waives the requirement that the content of kidney disease patient education services include the management of co-morbidities, including for the purpose of delaying the need for dialysis, under § 410.48(d)(1) of this chapter when such services are furnished to beneficiaries with CKD Stage V or ESRD, unless such content is relevant for the beneficiary.

(4) CMS waives the requirement that an outcomes assessment designed to measure beneficiary knowledge about CKD and its treatment be performed as part of a kidney disease patient education service under § 410.48(d)(5)(iii) of this chapter, provided that such outcomes assessment is performed by qualified staff within one month of the final kidney disease patient education service.

(5) Beginning the upon the expiration of the Public Health Emergency (PHE) for the COVID-19 pandemic, CMS waives the geographic and site of service originating site requirements in sections 1834(m)(4)(B) and 1834(m)(4)(C) of the Act and § 410.78(b)(3) and (4) of this chapter for purposes of kidney disease patient education services furnished by qualified staff via telehealth in accordance with this section, regardless of the location of the beneficiary or qualified staff. Beginning the upon the expiration of the Public Health Emergency (PHE) for the COVID-19 pandemic, CMS also waives the requirement in section 1834(m)(2)(B) of the Act and § 414.65(b) of this chapter that CMS pay a facility fee to the originating site with respect to telehealth services furnished to a beneficiary in accordance with this section at an originating site that is not one of the locations specified in § 410.78(b)(3) of this chapter.

(c)

(1) For kidney disease patient education services furnished on or after January 1, 2022, an ETC Participant may reduce or waive the 20 percent coinsurance requirement under section 1833 of the Act if all of the following conditions are satisfied:

(i) The individual or entity that furnished the kidney disease patient education services is qualified staff.

(ii) The qualified staff are not leased from or otherwise provided by an ESRD facility or related entity.

(iii) The kidney disease patient education services were furnished to a beneficiary described in § 410.48(b) or § 512.397(b)(2) who did not have secondary insurance that provides cost-sharing support for kidney disease patient education services on the date the services were furnished.

(iv) The kidney disease patient education services were furnished in compliance with the applicable provisions of § 410.48 and § 512.397(b).

(v) The ETC Participant bears the full cost of the reduction or waiver of the 20 percent coinsurance requirement under section 1833 of the Act. The reduction or waiver of the 20 percent coinsurance requirement under section 1833 of the Act shall not be financed by a third party, including but not limited to an ESRD facility or related entity.

(2) The ETC Participant must maintain and provide the government with access to records of the following information in accordance with § 512.135(b) and (c):

(i) The identity of the qualified staff who furnished the kidney disease patient education services for which the coinsurance was reduced or waived and the date such services were furnished.

(ii) The identity of the beneficiary who received the kidney disease patient education services for which the coinsurance was reduced or waived.

(iii) Evidence that the beneficiary who received the kidney disease patient education services coinsurance waiver was eligible to receive the kidney disease patient education services under the ETC Model and did not have secondary insurance that provides cost-sharing support for kidney disease patient education services.

(iv) The amount of the kidney disease patient education coinsurance reduction or waiver provided by the ETC Participant.

(3) The Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(2)) is available to protect the kidney disease patient education coinsurance waivers that satisfy the requirements of such safe harbor and paragraph (c)(1) of this section.

[85 FR 61362, Sept. 29, 2020, as amended at 86 FR 62025, Nov. 8, 2021; 87 FR 67302, Nov. 7, 2022]

Subpart D—Increasing Organ Transplant Access (IOTA) Model

Source: 89 FR 96445, Dec. 4, 2024, unless otherwise noted.

§ 512.400 Basis and scope.

(a) ***Basis.*** This subpart implements the test of the Increasing Organ Transplant Access (IOTA) Model under section 1115A(b) of the Act.

(b) ***Scope.*** This subpart sets forth the following:

(1) The method for selecting IOTA participants.

(2) The patient population.

(3) The methodology for IOTA participant performance assessment and scoring for purposes of the achievement domain, efficiency domain, and quality domain, including beneficiary attribution and transplant target calculation.

(4) The schedule and methodologies for the upside risk payment and downside risk payment.

(5) Data sharing.

(6) Other IOTA Model requirements.

(7) Beneficiary protections.

(8) Financial arrangements.

(9) Monitoring.

(10) Evaluation.

(11) Termination.

(12) Except as specifically noted in this subpart, the regulations under this subpart do not affect the applicability of other provisions affecting providers and suppliers under Medicare fee for service, including the applicability of provisions regarding payment, coverage, or program integrity.

(c) ***Applicability.*** IOTA participants are subject to the standard provisions for Innovation Center models specified in subpart A of this part 512 and in subpart K of part 403 of this chapter.

§ 512.402 Definitions.

For purposes of this subpart, the following definitions apply:

Achievement domain means the performance assessment category in which CMS assesses the IOTA participant's performance based on the number of transplants performed relative to the transplant target.

Alignment payment means a payment from an IOTA collaborator to an IOTA participant that is made in accordance with a sharing arrangement.

Annual attribution reconciliation means the yearly process in which CMS—

(1) Creates the final list of each IOTA participant's attributed patients for the prior performance year by retrospectively de-attributing from each IOTA participant any attributed patients that satisfy a criterion for de-attribution under § 512.414(c); and

(2) Creates a final list of each IOTA participant's attributed patients who remain attributed for the performance year being reconciled, subject to the attribution criteria under §§ 512.414(b)(1) and (2).

Annual attribution reconciliation list means the final cumulative record of attributed patients that CMS generates annually for whom each IOTA participant is accountable for during the applicable PY as described at § 512.414(c)(2).

Attributed patient means an IOTA waitlist patient or an IOTA transplant patient.

Attribution means the process by which CMS identifies the patients for whom each IOTA participant is accountable during the model performance period, as described in § 512.414.

Baseline year means a 12-month period within a 3-year historical baseline period, that begins 48 months (or 4 years) before the start of each model PY and ends 12 months (or 1 year) before the start of each model PY, as described in § 512.424.

Bypassed response means an organ offer not received due to expedited placement or a decision by a kidney transplant hospital to have all of its kidney transplant waitlist patients skipped during the organ allocation process based on a set of pre-defined filters selected by the kidney transplant hospital matching the characteristics of the potential organ to be transplanted.

Change in control means at least one of the following:

(1) The acquisition by any "person" (as this term is used in sections 13(d) and 14(d) of the Securities Exchange Act of 1934) of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Securities Exchange Act of 1934), directly or indirectly, of voting securities of the IOTA participant representing more than 50 percent of the IOTA participant's outstanding voting securities or rights to acquire such securities.

(2) The acquisition of the IOTA participant by any other individual or entity.

(3) Any merger, division, dissolution, or expansion of the IOTA participant.

(4) The sale, lease, exchange, or other transfer (in one transaction or a series of transactions) of all or substantially all the assets of the IOTA participant.

(5)

(i) The approval and completion of a plan of liquidation of the IOTA participant; or

(ii) An agreement for the sale or liquidation of the IOTA participant.

Collaboration agent means an individual or entity that is not an IOTA collaborator and that is a member of a PGP, NPPGP, or TGP that has entered into a distribution arrangement with the same PGP, NPPGP, or TGP in which he or she is an owner or employee, and where the PGP, NPPGP, or TGP is an IOTA collaborator.

Composite graft survival rate means the rolling unadjusted total number of functioning grafts relative to the total number of adult kidney transplants performed, as described in § 512.428.

CORF stands for comprehensive outpatient rehabilitation facility.

Critical access hospital (CAH) means a hospital as defined in section 1861(mm)(1) of the Act.

Days means calendar days unless otherwise specified by CMS.

Distribution arrangement means a financial arrangement between an IOTA collaborator that is an PGP, NPPGP, or TGP and a collaboration agent for the sole purpose of distributing some or all of a gainsharing payment received by the PGP, NPPGP, or TGP.

Distribution payment means a payment from an IOTA collaborator that is a PGP, NPPGP, or TGP to a collaboration agent, under a distribution arrangement, composed only of gainsharing payments.

Donation service area (DSA) means a geographical area of sufficient size to ensure maximum effectiveness in the procurement and equitable distribution of organs and that either includes an entire metropolitan statistical area (MSA) or does not include any part of such an area and that meets the standards of 42 CFR part 486 subpart G as defined in 42 CFR 486.302.

Downside risk payment means the lump sum payment the IOTA participant must pay to CMS after the close of a performance year if the IOTA participant's final performance score falls within the ranges specified in § 512.430.

Efficiency domain means the performance assessment category in which CMS assesses the IOTA participant's performance using the organ offer acceptance rate ratio as described in § 512.426.

EFT stands for electronic funds transfer.

Eligible attributed patient means an attributed patient that receives immunosuppressive drug coverage through Part B or Part D but that does not have secondary insurance that could provide cost sharing support.

Final performance score means the sum total of the scores earned by the IOTA participant across the achievement domain, efficiency domain, and quality domain for a given PY.

Gainsharing payment means a payment that is made from an IOTA participant to an IOTA collaborator, under a sharing arrangement as set forth in § 512.452 and in accordance with § 512.452(c).

HHA means a Medicare-enrolled home health agency.

Hospital has the meaning set forth in section 1861(e) of the Act.

Improvement benchmark rate means 120 percent of the IOTA participants' performance on the organ offer acceptance rate ratio as specified under § 512.426(c)(1)(ii)(A).

Initial attribution means the process by which CMS identifies and prospectively attributes patients who meet the criteria specified under § 512.414(a)(2)(b) to an IOTA participant prior to the model start date.

IOTA activities mean the activities related to promoting accountability for the quality, cost, and overall care for attributed patients and performance across the achievement domain, efficiency domain and quality domain, including any of the following:

(1) Managing and coordinating care.

(2) Encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery.

(3) The provision of items and services pre- or post-transplant in a manner that reduces costs and improves quality.

(4) Carrying out any other obligation or duty under the IOTA Model.

IOTA collaborator means the following Medicare-enrolled providers and suppliers that enter into a sharing arrangement with an IOTA participant:

(1) Nephrologist.

(2) ESRD facility.

(3) Skilled nursing facility (SNF).

(4) Home health agency (HHA).

(5) Long-term care hospital (LTCH).

(6) Inpatient rehabilitation facility (IRF).

(7) Physician.

(8) Nonphysician practitioner.

(9) Therapist in a private practice.

(10) CORF.

(11) Provider or supplier of outpatient therapy services.

(12) Physician group practice (PGP).

(13) Hospital.

(14) CAH.

(15) Non-physician provider group practice (NPPGP).

(16) Therapy group practice (TGP).

IOTA participant means a kidney transplant hospital, as defined at § 512.402, that is required to participate in the IOTA Model under § 512.412.

IOTA transplant patient means a kidney transplant patient who receives a kidney transplant at the age of 18 years of age or older from an IOTA participant at any time during the model performance period and meets the criteria set forth in § 512.414(b)(2).

IOTA waitlist patient means a kidney transplant waitlist patient, regardless of payer type and waitlist status, who meets all of the following:

(1) Is alive.

(2) 18 years of age or older.

(3) Registered on a waitlist (as defined in § 512.402) to one or more IOTA participants, as identified by the OPTN computer match program.

IRF stands for inpatient rehabilitation facility which must meet all of the following:

(1) The general criteria set forth in § 412.22.

(2) The criteria to be classified as a rehabilitation hospital or rehabilitation unit set forth in §§ 412.23(b), 412.25, and 412.29 for exclusion from the inpatient hospital prospective payment systems specified in § 412.1(a)(1).

Kidney transplant means the procedure in which a kidney is surgically transplanted from a living or deceased donor to a transplant recipient, either alone or in conjunction with any other organ(s).

Kidney transplant hospital means a transplant hospital with a Medicare approved kidney transplant program.

Kidney transplant patient means a patient who was a transplant candidate, as defined in § 121.2, and received a kidney transplant furnished by a kidney transplant hospital, regardless of payer type.

Kidney transplant waitlist patient means a patient who is a transplant candidate, as defined in § 121.2, and who is registered to a waitlist for a kidney at one or more kidney transplant hospitals.

LTCH stands for long-term care hospital that meets the requirements as stated in 42 CFR part 483 subpart B.

MA stands for Medicare Advantage.

Match run means a computerized ranking of transplant candidates based upon donor and candidate medical compatibility and criteria defined in OPTN policies.

Medicare kidney transplant means a kidney transplant furnished to an attributed patient in the IOTA Model whose primary or secondary insurance is Medicare fee for service (FFS) or MA, as identified in Medicare FFS claims with MS-DRGs 008, 019, 650, 651, and 652, or through OPTN data.

Member of the NPPGP or *NPPGP member* means a nonphysician practitioner or therapist who is an owner or employee of an NPPGP and who has reassigned to the NPPGP their right to receive Medicare payment.

Member of the PGP or *PGP member* means a physician, nonphysician practitioner, or therapist who is an owner or employee of the PGP and who has reassigned to the PGP their right to receive Medicare payment.

Member of the TGP or *TGP member* means a therapist who is an owner or employee of a TGP and who has reassigned to the TGP their right to receive Medicare payment.

Missing responses means organ offers that a kidney transplant hospital received from the OPO but did not submit a response (accepting or rejecting) in the allotted 1-hour timeframe from the time the offer was made per OPTN policy 5.6.B.

Military medical treatment facility (MTF) means both of the following:

(1) Any fixed facility of the Department of Defense that is outside of a deployed environment and used primarily for health care.

(2) Any other location used for purposes of providing health care. services as designated by the Secretary of Defense as defined in 10 U.S.C. 1073c(j)(3).

Model performance period means the 72-month period from the model start date and is comprised of 6 individual performance years.

Model-specific payment means a payment made by CMS only to IOTA participants, or a payment adjustment made only to payments made to IOTA participants, under the terms of the IOTA Model that is not applicable to any other providers or suppliers and includes, unless otherwise specified, both of the following:

(1) The IOTA Model upside risk payment.

(2) The IOTA Model downside risk payment.

Model start date means the date on which the model performance period begins, July 1, 2025.

MPSC stands for Membership and Professional Standards Committee.

National growth rate means the percentage increase or decrease in the number of kidney transplants performed over a 12-month period by all kidney transplant hospitals except for pediatric kidney transplant hospitals, as defined at § 512.402.

National Provider Identifier (NPI) means the standard unique health identifier used by health care providers for billing payors, assigned by the National Plan and Provider Enumeration System (NPPES) in accordance with 45 CFR part 162.

Neutral zone means the final performance score range in which the IOTA participant neither owes a downside risk payment to CMS nor receives an upside-risk payment from CMS, in accordance with § 512.430(b)(2).

Non-pediatric facility means a kidney transplant hospital that furnishes more than 50 percent of their kidney transplants annually to patients 18 years of age or older.

Nonphysician practitioner means (except for purposes of 42 CFR part 510 subpart G) one of the following:

(1) A physician assistant who satisfies the qualifications set forth at § 410.74(a)(2)(i) and (ii) of this chapter.

(2) A nurse practitioner who satisfies the qualifications set forth at § 410.75(b) of this chapter.

(3) A clinical nurse specialist who satisfies the qualifications set forth at § 410.76(b) of this chapter.

(4) A certified registered nurse anesthetist (as defined at § 410.69(b)).

(5) A clinical social worker (as defined at § 410.73(a)).

(6) A registered dietician or nutrition professional (as defined at § 410.134).

NPPGP means an entity that is enrolled in Medicare as a group practice, includes at least one owner or employee who is a nonphysician practitioner, does not include a physician owner or employee, and has a valid and active TIN.

OPTN computer match program means a set of computer-based instructions which compares data on a cadaveric organ donor with data on transplant candidates on the waiting list and ranks the candidates according to OPTN policies to determine the priority for allocating the donor organ(s).

Organ procurement and transplantation network or *OPTN* means the network established under section 372 of the Public Health Service Act.

Organ procurement organization or *OPO* means an entity designated by the Secretary under section 1138(b) of the Act and under 42 CFR 486.304.

Part B and Part D immunosuppressive drug cost sharing support means cost sharing support related to immunosuppressive drugs covered by Medicare Part B, the Medicare Part B Immunosuppressive Drug Benefit (Part B-ID), or Medicare Part D that is provided by an IOTA participant to an eligible attributed patient as codified at § 512.456.

Pediatric kidney transplant hospital means a kidney transplant hospital that performs 50 percent or more of its transplants in a 12-month period on patients under the age of 18.

Performance year (PY) means a 12-month period beginning on July 1 and ending on June 30 of each year during the model performance period.

PGP stands for physician group practice.

Physician has the meaning set forth in section 1861(r) of the Act.

Post-transplant period means the 90-day period following an attributed patient's receipt of a kidney transplant.

Preliminary performance assessment and payment calculations means the process by which CMS—

(1) Assesses each IOTA participant's performance in accordance with §§ 512.424, 512.426, 512.428; and

(2) Calculates performance-based payments in accordance with § 512.430.

PRA stands for panel-reactive antibody.

Provider of outpatient therapy services means an entity that is enrolled in Medicare as a provider of therapy services and furnishes one or more of the following:

(1) Outpatient physical therapy services as defined in § 410.60 of this chapter.

(2) Outpatient occupational therapy services as defined in § 410.59 of this chapter.

(3) Outpatient speech-language pathology services as defined in § 410.62 of this chapter.

Quality domain means the performance assessment category in which CMS assesses the IOTA participant's performance using a performance measure focused on improving the quality of transplant care as described in § 512.428.

Quality Health Information Network (QHIN) means a network of organizations that agrees to common terms and conditions regarding data exchange with each other (a "Common Agreement") and to the functional and technical requirements for such data exchange (as specified in the QHIN Technical Framework or "QTF") under section 4003(b) of the 21st Century Cures Act (Pub. L. 114-255).

Quarterly attribution list means the quarterly CMS-generated attributed patient list that CMS provides to the IOTA participant in advance of each quarter during the model performance period in accordance with § 512.414(c)(ii)(2).

Scientific Registry of Transplant Recipients or *SRTR* means the registry of information on transplant recipients established under section 373 of the Public Health Service Act.

Selected DSAs means those DSAs selected by CMS for purposes of selecting kidney transplant hospitals for participation in the IOTA Model.

Sharing arrangement means a financial arrangement to only share the upside risk payment and the downside risk payment lump-sum amount as set forth in § 512.452.

Single-organ kidney transplant means the procedure in which a kidney alone is surgically transplanted from a living or deceased donor to a transplant recipient alone.

SNF stands for skilled nursing facility that meets all applicable requirements in section of 1819 of the Act.

Targeted review process means the process in which an IOTA participant may dispute performance and payment calculations made, and issued, by CMS as set forth in § 512.434.

Taxpayer identification number (TIN) means a Federal taxpayer identification number or employer identification number as defined by the Internal Revenue Service in 26 CFR 301.6109-1.

TGP means an entity that is enrolled in Medicare as a therapy group in private practice, includes at least one owner or employee who is a therapist in private practice, does not include an owner or employee who is a physician or nonphysician practitioner, and has a valid and active TIN.

Therapist means one of the following individuals as defined at § 484.4 of this chapter:

(1) Physical therapist.

(2) Occupational therapist.

(3) Speech-language pathologist.

Therapist in private practice means a therapist that complies with one of the following special provisions:

(1) For physical therapists in private practice in § 410.60(c) of this chapter.

(2) For occupational therapists in private practice in § 410.59(c) of this chapter.

(3) For speech-language pathologists in private practice in § 410.62(c) of this chapter.

Transplant hospital means a hospital that furnishes organ transplants as defined in 42 CFR 121.2.

Transplant organ offer acceptance criteria means individualized patient acceptance parameters that kidney waitlist patients, as defined at § 512.402, may elect regarding the categories of organ offers they are prepared to accept for transplantation.

Transplant physician means a physician who provides non-surgical care and treatment to transplant patients before and after transplant as defined in 42 CFR 121.2.

Transplant program means a component within a transplant hospital which provides transplantation of a particular type of organ as defined in 42 CFR 121.2.

Transplant recipient means a person who has received an organ transplant as defined in 42 CFR 121.2.

Transplant target means the target number of kidney transplants calculated by CMS for the IOTA participant to measure the IOTA participant's performance in the achievement domain, as described in § 512.424.

Upside risk payment means the lump sum payment CMS makes to an IOTA participant if the IOTA participant's final performance score for a performance year falls within the payment range specified in § 512.430.

VA medical facility means a VA hospital, a VA community-based outpatient clinic, or a VA health care center, any of which must have at least one full-time primary care physician as defined in 38 CFR 17.1505. A Vet Center, or Readjustment Counseling Service Center, is not a VA medical facility.

Waitlist means a list of transplant candidates, as defined in 42 CFR 121.2, registered to the waiting list, as defined in 42 CFR 121.2, maintained by a transplant hospital in accordance with 42 CFR 482.94(b).

[89 FR 96445, Dec. 4, 2024, as amended at 91 FR 32869, June 1, 2026]

INCREASING ORGAN TRANSPLANT ACCESS MODEL SCOPE AND PARTICIPATION

§ 512.412 Participant eligibility and selection.

(a) ***Participant eligibility.*** A kidney transplant hospital is eligible to be selected as an IOTA participant, in accordance with the methodology described in paragraph (c) of this section, if the kidney transplant hospital meets all of the following criteria:

(1) The kidney transplant hospital annually performed 15 or more kidney transplants for patients aged 18 years or older, regardless of payer, each of the baseline years.

(2) The kidney transplant hospital annually performed more than 50 percent of its kidney transplants on patients 18 years of age or older each of the baseline years.

(3) The kidney transplant hospital is not an MTF or VA medical facility as defined at § 512.402.

(b) ***IOTA participant selection.*** CMS uses the following process to select IOTA participants for inclusion in the model.

(1) ***DSA stratification criteria.*** CMS uses the following criteria to stratify DSAs using the list of DSAs as of January 1, 2024:

(i) Census division of the DSA.

(ii) Total number of adult kidney transplants performed per year across eligible kidney transplant hospitals in the DSA during PY 1's baseline years.

(2) ***DSA stratification process.*** Prior to sampling DSAs, CMS uses the following steps to group DSAs into mutually exclusive groups.

(i) CMS assigns each DSA to one of the nine Census Divisions. CMS assigns each DSA to the Census Division where the majority of the DSA's population resides. CMS determines each DSA's population, and the share of a DSA's population in the applicable Census Division(s) using data from the 2020 Census.

(A) CMS assigns the Puerto Rico DSA to the South Atlantic Census Divisions.

(B) CMS combines the Middle Atlantic and New England Census Divisions and all DSAs therewithin creating eight groups of Census Divisions.

(ii) CMS identifies all kidney transplant hospitals located in each DSA within each Census Division group.

(iii) For each DSA within its assigned Census Division group, CMS identifies the eligible kidney transplant hospitals using the criteria specified in paragraph (a) of this section.

(iv) Using data from each of the baseline years for PY 1, CMS determines the average number of adult kidney transplants performed annually by eligible transplant hospitals located in each DSA as follows:

(A) Sums the number of adult kidney transplants performed across eligible kidney transplant hospitals in a DSA during each of the baseline years for PY 1; and

(B) Divides each DSA's sum resulting from the calculation in paragraph (b)(2)(iv)(A) of this section by three to determine the average number of adult kidney transplants furnished during the baseline years for PY 1.

(v) CMS separates DSAs in each Census Division group into two mutually exclusive groups of the same size, based on the average number of adult kidney transplants performed annually across the baseline years for PY 1, except where there are an odd number of DSAs within a Census Division group:

(A) DSAs with a higher number of adult kidney transplants per year across the baseline years for PY 1.

(B) DSAs with a lower number of adult kidney transplants per year across the baseline years for PY 1.

(vi) Where there are an odd number of DSAs within a Census Division group CMS uses the methodology set forth in paragraph (b)(3) of this section.

(3) ***Random sampling of DSAs.***

(i) For each DSA group within a Census Division group containing an odd number of DSAs, CMS randomly selects one DSA and determines its participation in the IOTA Model with a 50 percent probability.

(ii) CMS randomly samples, without replacement, 50 percent of the remaining DSAs in each group within each Census Division group created in paragraph (b)(2)(v) of this section.

(c) ***Selection of IOTA participants in selected DSAs.*** All eligible kidney transplant hospitals in the selected DSAs are required to participate in the IOTA Model.

(d) ***Notification of participation.*** CMS notifies IOTA participants of their selection to participate in the IOTA Model in a form and manner chosen by CMS at least 3 months prior to the start of the model performance period.

[89 FR 96445, Dec. 4, 2024, as amended at 91 FR 32870, June 1, 2026]

§ 512.414 Patient population.

(a) ***General.***

(1) CMS attributes kidney transplant waitlist patients and kidney transplant patients to IOTA participants based on the attribution criteria as described in paragraphs (b)(1) and (b)(2) of this section, for all of the following purposes:

(i) Sharing Medicare claims data for attributed beneficiaries with IOTA participants.

(ii) Assessing each IOTA participant's performance across the achievement domain, efficiency domain, and quality domain.

(iii) Determining performance-based payments paid to or by IOTA participants.

(2) Once a kidney transplant waitlist patient or kidney transplant patient is attributed to an IOTA participant, that respective patient may not opt out of attribution to an IOTA participant and remains attributed to the IOTA participant for the duration of the model performance period, unless the attributed patient meets the de-attribution criteria under paragraph (b)(3) of this section during annual attribution reconciliation as described in paragraph (b)(3) of this section.

(b) ***Patient attribution and de-attribution criteria*** —

(1) ***IOTA waitlist patient attribution.***

(i) At the time CMS conducts attribution, as described in paragraph (c) of this section, if a kidney transplant waitlist patient meets the definition of an IOTA waitlist patient, as defined at § 512.402, CMS attributes the kidney transplant waitlist patient as an IOTA waitlist patient to an IOTA participant.

(ii) [Reserved]

(2) ***IOTA transplant patient attribution.***

(i) At the time CMS conducts attribution, as described in paragraph (c) of this section, CMS attributes a kidney transplant patient as an IOTA transplant patient if the kidney transplant patient meets all of the following:

(A) The definition of an IOTA transplant patient, as defined at § 512.402.

(B) Is 18 years of age or older at the time of the patient's kidney transplant.

(C) Is alive.

(ii) [Reserved]

(3) ***De-attribution from an IOTA participant.*** During annual attribution reconciliation, CMS uses the fourth quarter attribution list for each IOTA participant and de-attributes any attributed patients who, as of the last day of the PY being reconciled, meet any of the following de-attribution criteria:

(i) An IOTA waitlist patient that was removed from and remains unregistered on an IOTA participant's kidney transplant waitlist.

(ii) An IOTA waitlist patient that has died at any point during the PY.

(iii) An IOTA transplant patient that has died at any point during the PY.

(iv) An IOTA transplant patient who experiences transplant failure at any point during the model performance period and has not rejoined an IOTA participant's kidney transplant waitlist or received another transplant from an IOTA participant before the last day of the respective PY.

(c) ***Attribution methodology.*** CMS employs the following methodology to attribute kidney waitlist patients and kidney transplant patients to an IOTA participant after identifying all kidney waitlist patients and kidney transplant patients that meet the attribution criteria as specified in paragraphs (b)(1) and (b)(2) of this section:

(1)

(i) ***Initial attribution.*** Prior to the model start date, CMS conducts initial attribution, as defined at § 512.402.

(ii) ***Initial attribution list.***

(A) CMS provides the initial attribution list to the IOTA participant no later than 15 days prior to the start of PY 1 and in a form and manner as determined by CMS.

(B) The initial attribution list includes a list of IOTA waitlist patients identified through initial attribution, effective on the model start date.

(2)

(i) ***Quarterly attribution.*** CMS conducts attribution, as defined at § 512.402, on a quarterly basis after the model start date, and updates the quarterly attribution list, as defined at § 512.402, for each IOTA participant, except in the event of termination in accordance with § 512.466.

(ii) ***Quarterly attribution list.*** CMS provides the quarterly attribution list, as defined at § 512.402, to the IOTA participant no later than 15 days prior to the start of each quarter and in a form and manner determined by CMS. The quarterly attribution list includes, at minimum, all of the following:

(A) A list of all newly attributed patients, whose attribution to the IOTA participant becomes effective on the first day of the relevant upcoming quarter.

(B) A list of all attributed patients who continue to be attributed to the IOTA participant from the previous quarter.

(C) The dates in which attribution began, changed, or ended, where applicable for attributed patients.

(D) The attributed patient's data sharing preferences under § 512.440(b).

(3)

(i) ***Annual attribution reconciliation.*** After the fourth quarter of each PY, CMS conducts annual attribution reconciliation as defined at § 512.402.

(ii) ***Annual attribution reconciliation list.*** CMS provides the annual reconciliation list to the IOTA participant before the second quarter of the following PY. Using the fourth quarter quarterly attribution list for each IOTA participant, the annual attribution reconciliation list identifies, at a minimum, all of the following, where applicable:

(A) A list of all attributed patients who remain attributed to the IOTA participant because they satisfied the attribution criteria under §§ 512.414(b)(1) and (2) for the respective PY.

(B) The dates in which attribution began, changed, or ended, where applicable.

(C) A list of all attributed patients who are de-attributed because they failed to satisfy the attribution criteria under § 512.414(b)(1) and (2).

(D) A list of all attributed patients who are de-attributed because they satisfy a de-attribution criterion under § 512.414(b)(3).

(E) The dates on which each attributed patient satisfied a de-attribution criterion as specified under § 512.414(b)(3).

(F) A list of the de-attribution criterion each attributed patient satisfied under § 512.414(b)(3).

[89 FR 96445, Dec. 4, 2024, as amended at 91 FR 32870, June 1, 2026]

PERFORMANCE ASSESSMENT AND SCORING

§ 512.422 Overview of performance assessment and scoring.

(a) ***General.***

(1) CMS establishes the performances measures described in §§ 512.424, 512.426, and 512.428 to assess IOTA participants in the achievement domain, efficiency domain and quality domain.

(2) CMS assigns each set of metrics within a domain a point value with the total possible points awarded to an IOTA participant across the three domains equaling 100, as described in §§ 512.424, 512.426, and 512.428.

(b) ***Data sources.***

(1) CMS uses Medicare claims data and Medicare administrative data about beneficiaries, providers, suppliers, and data from the OPTN, to calculate performance for the IOTA participant based on the methodologies under §§ 512.424, 512.426, and 512.428.

(2) CMS may also use model-specific data reported by an IOTA participant to CMS under the IOTA Model to calculate IOTA participant performance in the domains.

§ 512.424 Achievement domain.

(a) ***General.***

(1) After each PY, CMS calculates the number of kidney transplants that each IOTA participant performed for the respective PY, in accordance with the provisions in paragraph (d) of this section.

(2) CMS compares the number of kidney transplants that an IOTA participant performed during the PY to the IOTA participant's transplant target to determine the IOTA participant's score for the achievement domain.

(b) ***Transplant target methodology.*** CMS determines the IOTA participant's transplant target for each PY as follows:

(1) ***Analysis of baseline years.*** CMS analyzes the baseline years for the relevant PY and identifies:

(i) The mean number of deceased donor kidney transplants furnished by the IOTA participant to patients 18 years of age or older across the baseline years, as defined at § 512.402; and

(ii) The mean number of living donor kidney transplants furnished by the IOTA participant to patients 18 years of age or older across the baseline years, as defined at § 512.402.

(2) ***Mean of kidney transplants.*** CMS sums the numbers in paragraphs (b)(1)(i) and (ii) of this section.

(3) ***National growth rate calculation.*** CMS calculates the national growth rate, as defined at § 512.402, using the baseline years for the relevant PY as follows:

(i) Subtracts the total number of kidney transplants furnished to patients 18 years of age or older during the second baseline year from the total number of kidney transplants furnished to patients 18 years of age or older during the third baseline year.

(ii) Divides the amount resulting from the calculation in paragraph (b)(3)(i) of this section by the total number of kidney transplants furnished to patients 18 years of age or older during the third baseline year. The resulting amount is the national growth rate for the relevant PY.

(4) ***Calculation of transplant target.*** If the national growth rate calculated in paragraph (b)(3) of this section is—

(i) Positive, CMS multiples that national growth rate by the sum calculated in paragraph (b)(2) of this section. The resulting amount is an IOTA participant's transplant target for the relevant PY; or

(ii) Negative, CMS does not multiply the national growth rate by the sum calculated in paragraph (b)(2) of this section. The IOTA participant's transplant target for the relevant PY is the sum calculated in paragraph (b)(2) of this section.

(c) ***Notification of transplant target.*** CMS notifies the IOTA participant of the transplant target by the first day of the start of each PY in a form and manner determined by CMS.

(d) ***Calculation of kidney transplants performed during the PY.***

(1)

(i) After each PY, CMS counts the number of kidney transplants performed by the IOTA participant on patients who were 18 years of age or older at the time of transplant, during the PY.

(ii) CMS identifies kidney transplants performed by the IOTA participant using OPTN data, regardless of payer, and Medicare claims data.

(2) CMS counts each kidney transplant described in paragraph (d)(1) of this section as one transplant.

(e) [Reserved]

(f) ***Achievement domain scoring.*** For each PY, CMS awards the IOTA participant zero to 60 points for its performance in the achievement domain.

(1) CMS compares the total number of kidney transplants identified under paragraph (d)(2) of this section to the IOTA participant's transplant target, as described in paragraph (b) of this section.

(2) CMS uses the following scoring methodology to determine an IOTA participant's score on the achievement domain.

Table 1 to Paragraph (f)(2)—IOTA Model Achievement Domain Scoring Methodology

Performance Relative to Transplant Target	Lower Bound Condition	Upper Bound Condition	Points Earned
125% of transplant target	Equals 125%	Greater than 125%	60
120% of transplant target	Equals 120%	Less than 125%	55
115% of transplant target	Equals 115%	Less than 120%	50
105% of transplant target	Equals 105%	Less than 115%	40
95% of transplant target	Equals 95%	Less than 105%	30
85% of transplant target	Equals 85%	Less than 95%	20
75% of transplant target	Equals 75%	Less than 85%	10
75% of transplant target	N/A	Less than 75%	0

§ 512.426 Efficiency domain.

(a) ***General.*** For each PY, CMS assesses each IOTA participant on the metric described in paragraph (b) of this section to determine the IOTA participant's score for the efficiency domain.

(b) ***Metric included in the efficiency domain.*** For each PY, CMS assesses the IOTA participant on the following metric:

(1) ***Organ-offer acceptance rate ratio.*** For each PY, CMS calculates the organ-offer acceptance rate ratio by dividing the number of kidneys the IOTA participant accepted by the risk-adjusted number of expected organ-offer acceptances using SRTR's methodology as described in equation 1 to paragraph (b)(1) introductory text of this section.

Equation 1 to Paragraph (b)(1) Introductory Text—Organ Offer Acceptance Rate Ratio

$$Organ\ Offer\ Acceptance\ Rate\ Ratio = \frac{Number\ of\ Acceptances + 2}{Number\ of\ Expected\ Acceptances + 2}$$

(i) CMS uses both of the following:

(A) SRTR data to calculate the organ-offer acceptance rate ratio.

(B) SRTR's adult kidney model strata risk-adjustment methodology and most available set of coefficients to calculate the number of expected organ-offer acceptances.

(ii) CMS includes all of the following kidney offers when calculating the organ-offer acceptance rate ratio for the IOTA participant:

(A) Offers that are ultimately accepted and transplanted.

(B) Offers to candidates on a single organ waitlist (except for kidney/pancreas candidates that are also listed for kidney alone).

(iii) CMS excludes the following kidney offers when calculating the organ-offer acceptance rate:

(A) Offers with multiple match runs from the same donor combined and duplicate offers.

(B) Offers with no match run acceptances.

(C) Offers that occurred after the last acceptance in a match run.

(D) Offers with a missing or bypassed response.

(E) Offers to multi-organ candidates (except for kidney/pancreas candidates that are also listed for kidney alone).

(c) ***Efficiency domain scoring.*** For each PY, CMS awards the IOTA participant 0 to 20 points for its performance in the efficiency domain.

(1) ***General.*** CMS determines the IOTA participant's score for the efficiency domain for each PY by taking the IOTA participant's score for the organ offer acceptance rate ratio, as described under paragraph (c)(2) of this section. This number is the IOTA participant's score for the efficiency domain for the PY.

(2) ***Scoring for organ offer acceptance rate ratio.*** CMS calculates the IOTA participant's achievement score, as described in paragraph (c)(2)(i) of this section, and improvement score, as described under paragraph (c)(2)(ii) of this section, for the organ offer acceptance rate ratio, compares the IOTA participant's achievement score and improvement score and awards to the IOTA participant the points that correspond to the higher score.

(i) ***Achievement scoring.*** CMS calculates the IOTA participant's achievement score based on the IOTA participant's performance on organ offer acceptance rate ratio relative to national ranking, including all eligible kidney transplant hospitals, using the scoring methodology described in table 1 to paragraph (c)(1)(i) of this section.

Table 1 to Paragraph (c)(1)(i)—IOTA Model Organ Offer Acceptance Rate Ratio Achievement Scoring

Performance Relative to National Ranking	Lower Bound Condition	Upper Bound Condition	Points Earned
80th Percentile	Equals 80th percentile	Greater than 80th percentile	20
60th Percentile	Equals 60th percentile	Less than 80th percentile	15
40th Percentile	Equals 40th percentile	Less than 60th percentile	10
20th Percentile	Equals 20th percentile	Less than 40th percentile	6
20th Percentile	N/A	Less than 20th percentile	0

(ii) ***Improvement scoring.*** CMS compares the IOTA participant's organ offer acceptance rate ratio during the PY, calculated as described under paragraph (c)(1)(i) of this section, to the IOTA participant's improvement benchmark rate, calculated as described under paragraph (c)(1)(ii)(A) of this section.

(A) ***Improvement benchmark rate.*** CMS calculates an improvement benchmark rate for the IOTA participant. To determine an IOTA participant's improvement benchmark rate for a given PY, CMS multiplies an IOTA participant's organ offer acceptance rate ratio during the third baseline year by 120 percent.

(B) ***Improvement score calculation.*** For each PY, CMS uses the following methodology to determine each IOTA participant's improvement score on the organ offer acceptance rate ratio:

(*1*) If the IOTA participant's organ-offer acceptance rate ratio is greater than or equal to the improvement benchmark rate, CMS awards the IOTA participant 15 points in the efficiency domain.

(*2*) If the IOTA participant's organ offer acceptance rate ratio is equal to or less than the IOTA participant's organ-offer acceptance rate ratio in the third baseline year for that respective PY, CMS awards the IOTA participant 0 points in the efficiency domain.

(*3*) If the IOTA participant's organ offer acceptance rate ratio is greater than the IOTA participant's organ-offer acceptance rate ratio in the third baseline year for that respective PY but less than the improvement benchmark rate, CMS uses the following equation:

Equation 2 to Paragraph (c)(2)(ii)(B)(*3*)—IOTA Model Organ Offer Acceptance Rate Ratio Improvement Scoring Equation

$$15\ x\frac{Rate\ Earned\ in\ Performance\ Year\ -Third\ Baseline\ Year\ Rate}{Improvment\ Benchmark\ Rate-Third\ Baseline\ Year\ Rate}$$

§ 512.428 Quality domain.

(a) ***General.*** For each PY, CMS assesses each IOTA participant on the metric described under paragraph (b)(1) of this section to determine the IOTA participant's quality domain score, as described under paragraphs (c) through (e) of this section, for the quality domain.

(b) ***Metrics included in the quality domain.*** For each PY, CMS assesses each IOTA participant using the following quality metrics:

(1) ***Post-transplant graft survival.*** For each PY, CMS calculates an IOTA participant's composite graft survival rate by dividing the cumulative number of all functioning kidney grafts for the IOTA participant's IOTA transplant patients by the cumulative number of all kidney transplants performed by the IOTA participant during the first PY and all subsequent PYs on patients 18 years or older at the time of the transplant, as described in equation 1 to paragraph (b)(1) introductory text of this section.

Equation 1 to Paragraph (b)(1) Introductory Text—Composite Graft Survival Rate

$$Composite\ Graft\ Survival\ Rate\ =\frac{\#\ of\ Functioning\ Grafts}{\#\ of\ Completed\ Kidney\ Transplants}$$

(i) For the first PY, CMS calculates the IOTA participant's composite graft survival rate based solely on the number of functioning grafts furnished to IOTA transplant patients during that PY and the number of completed kidney transplants during that PY, as described in paragraph (b)(1) of this section.

(ii) For all subsequent PYs, CMS calculates the IOTA participant's cumulative composite graft survival rate using the same calculation methodology described in paragraph (b)(1) of this section and in accordance with paragraph (b)(2) of this section.

(iii) CMS excludes the following from the numerator when calculating the composite graft survival rate:

(A) Graft failure, based on OPTN adult kidney transplant recipient follow-up forms for all completed kidney transplants to determine failed grafts as defined by SRTR.

(B) Re-transplant.

(C) Death.

(D) Patients who are under the age of 18 years of age at the time of the kidney transplant.

(E) Multi-organ transplants (except for kidney/pancreas transplants).

(iv)

(A) When calculating the composite graft survival rate, CMS only includes single-organ kidney transplants, as defined at § 512.402, and kidney/pancreas transplants for patients who are 18 years of age and older at the time of the kidney transplant in the number of kidney transplants performed by the IOTA participant during each PY in the denominator.

(B) CMS identifies kidney transplants performed by the IOTA participant using OPTN data, regardless of payer, and Medicare claims data.

(2) ***Risk-adjustment transplant recipient and donor characteristics.*** In accordance with paragraphs (b)(1) through (3) of this section, CMS risk-adjusts the composite graft survival rate using SRTR's adult kidney graft survival first-year outcomes variables in accordance with paragraphs (3)(i) through (iii) of this section.

(3) ***Risk-adjustment methodology*** —

(i) ***Calculation of Observed Composite Graft Survival Rate.*** In accordance with paragraph (b)(1) of this section, CMS calculates the observed composite graft survival rate by dividing the number of functioning grafts plus two by the total number of completed kidney transplants plus two, as described in equation 2 to paragraph (b)(3)(i) of this section.

Equation 2 *to* Paragraph *(b)(3)(i): Observed Composite Graft Survival Rate Calculation.*

$$Composite\ Graft\ Survival\ Rate_{Observed} = \frac{\#\ of\ Functioning\ Grafts + 2}{\#\ of\ Completed\ Kidney\ Transplants + 2}$$

(ii) ***Risk score calculation methodology.*** CMS calculates a risk score for each IOTA participant as follows:

(A) ***Expected graft failure rate Calculation.***

(*1*) CMS calculates the expected graft failure rate using SRTR's methodology as described in equation 3 to paragraph (b)(3)(ii)(A)(1).

Equation 3 *to* Paragraph *(b)(3)(ii)(A)(1): Expected Graft Failure Rate Calculation.*

$$Prob(failure) = 1 - S_0 t) exp^{(\beta X)}$$

(*2*) CMS uses both of the following:

(*i*) SRTR adult kidney graft survival first-year post-transplant risk-adjustment models for both deceased donor and living donor kidney transplants.

(*ii*) SRTR's most available set of coefficients.

(B) ***National graft failure rate calculation.***

(*1*) CMS calculates the national graft failure rate by dividing the number of graft failures in a given PY by the number of completed kidney transplants in a given PY, as described in equation 4 to paragraph (b)(3)(ii)(B)(1) of this section.

Equation 4 to Paragraph *(b)(3)(ii)(B)(1): National Graft Failure Rate Calculation.*

$$National\ Graft\ Failure\ Rate = \frac{Number\ of\ Graft\ Failures}{Number\ of\ Completed\ Kidney\ Transplants}$$

(2) When calculating the national graft failure rate, CMS excludes all of the following:

(*i*) Patients who are under the age of 18 years of age at the time of the kidney transplant.

(*ii*) Pediatric kidney transplant hospitals as defined at § 512.402.

(*iii*) Multi-organ transplants (except for kidney/pancreas transplants).

(3) In accordance with the provisions in paragraph (b)(3)(ii)(B)(2) of this section, CMS includes kidney transplant patients who have experienced any of the following in the numerator when calculating the national graft failure rate:

(*i*) Graft failure, based on OPTN adult kidney transplant recipient follow-up forms for all completed kidney transplants to determine failed grafts as defined by SRTR.

(*ii*) Re-transplant.

(*iii*) Death.

(4) When calculating the national graft failure rate, CMS only includes single-organ kidney transplants, as defined at § 512.402, and kidney/pancreas transplants for patients who are 18 years of age and older at the time of the kidney transplant in the number of kidney transplants performed during the given PY in the denominator.

(C) ***Risk Score Calculation.*** CMS calculates the risk score for each IOTA participant by dividing the amount resulting from the calculation in paragraph (b)(3)(ii)(A) by the amount resulting from the calculation in paragraph (b)(3)(ii)(B) as described in equation 5 to paragraph (b)(3)(ii)(C) of this section.

Equation 5 to Paragraph *(b)(3)(ii)(C): Risk Score Calculation.*

$$Risk\ Score = \frac{Expected\ Graft\ Failure\ Rate_{IOTA\ Participant}}{Graft\ Failure\ Rate_{National}}$$

(iii) ***Risk-Adjusted Composite Graft Survival Rate Calculation.*** CMS calculates the risk-adjusted composite graft survival rate for each IOTA participant by multiplying the amount resulting from the calculation in paragraph (b)(3)(i) of this section by the amount resulting from the calculation in paragraph (b)(3)(ii) of this section, as described in equation 6 to paragraph (b)(3)(iii) of this section.

Equation 6 *to* Paragraph *(b)(3)(iii): Risk-Adjusted Composite Graft Survival Rate Calculation*

$$Composite\ Graft\ Survival\ Rate_{Risk-Adjusted} = Composite\ Graft\ Survival\ Rate_{Observed}\ x\ Risk\ Score$$

(c) ***Quality domain scoring.*** For each PY, CMS awards the IOTA participant zero to 20 points for the IOTA participant's performance in the quality domain, in accordance with the following:

(1) For composite graft survival rate, as described under paragraph (d) of this section, the IOTA participant may receive up to 20 points.

(2) [Reserved]

(d) ***Composite graft survival rate scoring.*** CMS awards points to the IOTA participant based on the IOTA participant's performance on the composite graft survival rate, as described in paragraph (b)(1) of this section, ranked nationally, inclusive of all eligible kidney transplant hospitals. CMS awards points to the IOTA participant for composite graft survival rate as described in table 1 to paragraph (d) of this section:

TABLE 1 TO PARAGRAPH (d)—IOTA MODEL COMPOSITE GRAFT SURVIVAL RATE SCORING

Performance relative to national ranking	Lower bound condition	Upper bound condition	Points earned
87.5th percentile	Equals 87.5th percentile	Greater than 87.5th percentile	20
75th percentile	Equals 75th percentile	Less than 87.5th percentile	18
62.5th percentile	Equals 62.5th percentile	Less than 75th percentile	15
50th percentile	Equals 50th percentile	Less than 62.5th percentile	13
37.5th percentile	Equals 37.5th percentile	Less than 50th percentile	10
25th percentile	Equals 25th percentile	Less than 37.5th percentile	8
12.5th percentile	Equals 12.5th percentile	Less than 25th percentile	5
12.5th percentile	N/A	Less than 12.5th percentile	0

[89 FR 96445, Dec. 4, 2024, as amended at 91 FR 32870, June 1, 2026]

PAYMENT

§ 512.430 Upside risk payment, downside risk payment, and neutral zone.

(a) ***General.*** CMS determines if an IOTA participant qualifies for an upside risk payment, downside risk payment, or the neutral zone for each PY based on the IOTA participant's final performance score, in accordance with paragraphs (b)(1) through (3) of this section.

(b) ***Upside risk payment, neutral zone, and downside risk payment calculation methodology*** —

(1) ***Upside risk payment calculation methodology.*** If in PYs 1-6 the IOTA participant's final performance score is above 60 points, CMS calculates the IOTA participant's upside risk payment as follows:

(i) Subtracts 60 from the IOTA participant's final performance score.

(ii) Divides the amount resulting from the calculation in paragraph (b)(1)(i) of this section by 40.

(iii) Multiplies the amount resulting from the calculation in paragraph (b)(1)(ii) of this section by $15,000.

(iv) Multiplies the amount resulting from the calculation in paragraph (b)(1)(iii) of this section by the total number of Medicare kidney transplants performed by the IOTA participant during the PY.

(2) ***Neutral zone.***

(i) For PY 1, an IOTA participant with a final performance score below 60 points qualifies for the neutral zone and neither owes a downside risk payment to CMS nor receives an upside risk payment from CMS.

(ii) For PYs 2 through 6, if an IOTA participant's final performance is between 40 to 60 points (inclusive), the IOTA participant qualifies for the neutral zone.

(3) ***Downside risk payment calculation methodology.*** If an IOTA participant is below 40 points in PYs 1 through 6, the IOTA participant qualifies for a downside risk payment. The downside risk payment is calculated as follows:

(i) For PY 1, this paragraph does not apply, and the IOTA participant does not owe a downside risk payment to CMS.

(ii) For PYs 2 through 6, CMS calculates the IOTA participant's downside risk payment as follows:

(A) Subtracts the IOTA participant's final performance score from 40.

(B) Divides the amount resulting from the calculation in paragraph (b)(3)(ii)(A) of this section by 40.

(C) Multiplies the amount resulting from the calculation in paragraph (b)(3)(ii)(B) of this section by $2,000.

(D) Multiplies the amount resulting from the calculation in paragraph (b)(3)(ii)(C) of this section by the total number of Medicare kidney transplants performed by the IOTA participant during the PY to calculate the amount of the IOTA participant's downside risk payment.

(c) [Reserved]

(d) ***Upside risk payment and downside risk payment timeline.***

(1) CMS conducts and calculates preliminary performance assessment and payment calculations at least 3 to 6 months after the end of each PY.

(2) CMS notifies the IOTA participant of their preliminary performance assessment and payment calculations in a form and manner determined by CMS at least 5 to 9 months after the end of each PY.

(3) CMS gives IOTA participants 30 days to review preliminary performance assessment and payment calculations and request targeted reviews under § 512.434.

(4) CMS notifies the IOTA participant of their final performance score and any associated upside risk payment or downside risk payment at least 30 days after notifying the IOTA participant of their preliminary performance assessment and payment calculations.

(5) ***Upside risk payment.*** After CMS notifies the IOTA participant of their final performance score and any associated upside risk payment, and by a date determined by CMS, CMS issues the upside risk payment to the tax identification number (TIN) on file for the IOTA participant in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS).

(6) ***Downside risk payment.*** After CMS notifies the IOTA participant of their final performance score and any associated downside risk payment and by a date determined by CMS, CMS issues a demand letter to the TIN on file for the IOTA participant in PECOS for any downside risk payment owed to CMS.

(i) CMS includes all of the following details in the demand letter:

(A) IOTA participant performance in the model.

(B) Amount of downside risk payment owed to CMS by the IOTA participant.

(C) How the IOTA participant may make payments to CMS.

(ii) The IOTA participant must pay the downside risk payment to CMS in a single payment within 60 days after the date on which the demand letter is issued. If full payment is not received by CMS within 60 days after demand is made, CMS will invoke all legal means to collect the debt, including referral of the remaining debt to the United States Department of the Treasury, in accordance with 31 U.S.C. 3711(g).

[89 FR 96445, Dec. 4, 2024, as amended at 91 FR 32871, June 1, 2026]

§ 512.434 Targeted review.

(a) ***General.*** Subject to the limitations on review in paragraph (c) of this section, an IOTA participant may submit a targeted review request for one or more calculations made, and issued by, CMS within the preliminary performance assessment and payment calculations, if either of the following occur:

(1) The IOTA participant believes an error occurred in calculations due to data quality or other issues.

(2) The IOTA participant believes an error occurred in calculations due to misapplication of methodology.

(b) ***Requirements.*** The request must satisfy the following criteria:

(1) Be submitted within 30 days, or another time period as specified by CMS, of receiving its preliminary performance assessment and payment calculations from CMS.

(2) Include supporting information in a form and manner as specified by CMS.

(c) ***Limitations on review.***

(1) CMS does not provide IOTA participants the ability to dispute the policy or methodology, as the targeted review process would be limited to the dispute of calculations. CMS would not consider targeted review requests regarding, without limitation, the following:

(i) The selection of the kidney transplant hospital to be an IOTA participant.

(ii) The attribution of IOTA waitlist patients and the attribution of IOTA transplant patients to the IOTA participant, or to any other kidney transplant hospital selected for participation in the IOTA Model, or to any kidney transplant hospital not selected for participation in the IOTA Model.

(iii) The methodology used for determining the achievement domain, efficiency domain, and quality domain.

(iv) The methodology used for calculating and assigning points for each metric within the achievement domain, efficiency domain, and quality domain.

(v) The methodology used for calculating the payment amount per Medicare kidney transplant paid to an IOTA participant.

(2) CMS may review a targeted review request that includes one or more of the limitations in paragraph (c)(1) of this section, provided that all remaining considerations of the request meet all other criteria for consideration by CMS in this section.

(d) ***Targeted review process.*** The IOTA participant must submit a request for targeted review in accordance with paragraphs (a) through (c) of this section. The process for a targeted review is as follows:

(1) ***Initial and final assessments.*** Upon receipt of a targeted review request from an IOTA participant CMS conducts an initial and final assessment as follows:

(i) ***Initial assessment.***

(A) CMS determines if the targeted review request meets the targeted review requirements in paragraph (b) of this section and contains sufficient information to substantiate the request.

(B) If the request is not compliant with paragraphs (a) through (c) of this section or requires additional information:

(*1*) CMS follows up with the IOTA participant to request additional information in a form and manner as specified by CMS.

(*2*) The IOTA participant must respond within 30 days of CMS's request for additional information in a form and manner as specified by CMS.

(*3*) An IOTA participant's non-responsiveness to the request for additional information from CMS may result in the closure of the targeted review request.

(ii) ***Final assessment.***

(A) Upon completion of an initial assessment, as described in paragraph (d)(1)(i) of this section, CMS determines whether it erred in calculation, as disputed by the IOTA participant.

(B) If a calculation error is found as a result of an IOTA participant's targeted review request—

(*1*) CMS—

(*i*) Notifies the IOTA participant within 30 days of any findings in a form and manner as specified by CMS; and

(*ii*) Resolves and corrects any resulting error or discrepancy in the amount of the upside risk payment or downside risk payment in a time and manner as determined by CMS.

(2) CMS' correction of any error or discrepancy may delay the effective date of an IOTA participant's upside risk payments or downside risk payments.

(2) ***Targeted review decisions.*** Targeted review decisions made by CMS are final, unless submitted for administrative review as described in § 512.190.

§ 512.436 Extreme and uncontrollable circumstances.

(a) ***General.*** CMS—

(1) Applies determinations made under the Quality Payment Program with respect to whether an extreme and uncontrollable circumstance has occurred and the affected area during the PY; and

(2) Has sole discretion to determine the period during which an extreme and uncontrollable circumstance occurred and the percentage of attributed patients residing in affected areas.

(b) ***Impact on payments.*** In the event of an extreme and uncontrollable circumstance, as described in paragraph (a) of this section, CMS may adjust the magnitude and direction of the IOTA participant's upside or downside risk payment, if applicable, prior to recoupment or payment, if the IOTA participant is participating in the IOTA Model when CMS has declared such an emergency period. CMS may determine any adjustment made based in part on the following:

(1) The percentage of total months during the PY affected by the extreme and uncontrollable circumstance.

(2) The percentage of attributed patients who reside in an area affected by the extreme and uncontrollable circumstance.

[89 FR 96445, Dec. 4, 2024, as amended at 91 FR 32871, June 1, 2026]

DATA SHARING

§ 512.440 Data sharing.

(a) ***General.*** CMS shares certain beneficiary-identifiable data as described in paragraph (b) of this section and certain aggregate data as described in paragraph (c) of this section with IOTA participants regarding attributed patients who are Medicare beneficiaries and performance under the model.

(b) ***Beneficiary-identifiable data.*** CMS shares beneficiary-identifiable data with IOTA participants as follows:

(1) CMS makes available certain beneficiary-identifiable data described in paragraphs (b)(4) and (5) of this section for IOTA participants to request for purposes of conducting 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 their attributed patients who are Medicare beneficiaries.

(2) An IOTA participant that wishes to receive beneficiary-identifiable data for its attributed patients who are Medicare beneficiaries must do all of the following:

(i) Submit a formal request for the data, on an annual basis in a manner and form and by a date specified by CMS, which identifies the data being requested and attests that—

(A) The IOTA participant is requesting this beneficiary-identifiable data as a HIPAA covered entity or as a business associate, as those terms are defined at 45 CFR 160.103, to the IOTA participant's providers and suppliers who are HIPAA covered entities; and

(B) The IOTA participant's request reflects the minimum data necessary, as set forth in paragraph (b)(6) of this section, for the IOTA participant 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.

(ii) Limit the request to Medicare beneficiaries whose name appears on the quarterly attribution list who have been notified in compliance with § 512.450 that the IOTA participant has requested access to beneficiary-identifiable data, and who did not decline having their claims data shared with the IOTA participant as provided in paragraph (b)(7) of this section.

(iii) Sign and submit a data sharing agreement with CMS as set forth in paragraph (b)(8) of this section.

(3) CMS shares beneficiary-identifiable data with an IOTA participant on the condition that the IOTA participant, its IOTA collaborators, and other individuals or entities performing functions or services related to the IOTA participant'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 sharing agreement described in paragraph (b)(8) of this section.

(4) CMS omits from the beneficiary-identifiable data any information that is subject to the regulations in 42 CFR part 2 governing the confidentiality of substance use disorder patient records.

(5) The beneficiary-identifiable data will include, when available, the following information:

(i) ***Quarterly attribution lists.*** For the relevant PY, CMS shares with the IOTA participant the quarterly attribution lists, which will include but may not be limited to the following information for each attributed patient:

(A) The year that CMS attributed the patient to the IOTA participant.

(B) The effective date of the patient's attribution to the IOTA participant.

(C) The effective date of the patient's de-attribution from the IOTA participant and the reason for such removal (if applicable).

(D) For Medicare beneficiaries, the attributed patient's data sharing preference.

(ii) ***Beneficiary-identifiable claims data.*** CMS makes available certain beneficiary-identifiable claims data for retrieval by IOTA participants no later than 1 month after the start of each PY, in a form and manner specified by CMS. IOTA participants may retrieve the following data at any point during the relevant PY. This claims data includes all of the following:

(A) Three years of historical Parts A, B, and D claims data files from the 36 months immediately preceding the effective date of each attributed patient who is a Medicare beneficiary's attribution to the IOTA participant.

(B) Monthly Parts A, B, and D claims data files for attributed patients who are Medicare beneficiaries.

(C) Monthly Parts A, B, and D claims data files for Medicare beneficiaries who have been de-attributed from the IOTA participant for claims with a date of service before the date the Medicare beneficiary was de-attributed from the IOTA participant.

(6) The IOTA participant must limit its attributed Medicare beneficiary identifiable data requests to the minimum necessary to accomplish a permitted use of the data.

(i) The minimum necessary Parts A and B data elements may include but are not limited to the following data elements:

(A) Medicare beneficiary identifier (ID).

(B) Procedure code.

(C) Gender.

(D) Diagnosis code.

(E) Claim ID.

(F) The from and through dates of service.

(G) The provider or supplier ID.

(H) The claim payment type.

(I) Date of birth and death, if applicable.

(J) Tax identification number (TIN).

(K) National provider identifier (NPI).

(ii) The minimum necessary Part D data elements may include but are not limited to the following data elements:

(A) Beneficiary ID.

(B) Prescriber ID.

(C) Drug service date.

(D) Drug product service ID.

(E) Quantity dispensed.

(F) Days supplied.

(G) Brand name.

(H) Generic name.

(I) Drug strength.

(J) TIN.

(K) NPI.

(L) Indication if on formulary.

(M) Gross drug cost.

(7)

(i)

(A) IOTA participants must send Medicare beneficiaries a notification about the IOTA Model and the opportunity to decline claims data sharing as required under § 512.450.

(B) Such notifications must do both of the following:

(*1*) State that the IOTA participant may have requested beneficiary-identifiable claims data about the Medicare beneficiary for purposes of its care coordination, quality improvement work, and population-based activities relating to improving health or reducing health care costs.

(*2*) Inform the Medicare beneficiary how to decline having his or her claims information shared with the IOTA participant in the form and manner specified by CMS.

(ii) Medicare beneficiary requests to decline claims data sharing remain in effect unless and until a beneficiary subsequently contacts CMS to amend that request to permit claims data sharing with IOTA participants.

(iii) The opportunity to decline having claims data shared with an IOTA participant under paragraph (b)(7)(i) of this section does not apply to any of the following:

(A) The aggregate data that CMS provides to IOTA participants under paragraph (c) of this section.

(B) The initial attribution lists that CMS provides to IOTA participants as defined at § 512.402 and specified under § 512.414(c)(1)(ii).

(C) The quarterly attribution lists that CMS provides to IOTA participants as defined at § 512.402 and specified under § 512.414(c)(2)(ii).

(D) The annual attribution reconciliation list that CMS provides to IOTA participants as defined at § 512.402 and specified under § 512.414(c)(3)(ii).

(8)

(i) If an IOTA participant wishes to retrieve any beneficiary-identifiable data specified in paragraph (b) of this section, the IOTA participant must complete and submit, on an annual basis, a signed data sharing agreement, to be provided in a form and manner specified by CMS, under which the IOTA participant agrees to all of the following:

(A) To comply with the requirements for use and disclosure of this beneficiary-identifiable data that are imposed on covered entities by the HIPAA regulations at 45 CFR part 160 and part 164, subparts A and E, and the requirements of the IOTA Model set forth in this part.

(B) To comply with additional privacy, security, breach notification, and data retention requirements specified by CMS in the data sharing agreement.

(C) To contractually bind each downstream recipient of the beneficiary-identifiable data that is a business associate of the IOTA participant, including all IOTA collaborators, to the same terms and conditions to which the IOTA participant is itself bound in its data sharing agreement with CMS as a condition of the business associate's receipt of the beneficiary-identifiable data retrieved by the IOTA participant under the IOTA Model.

(D) That if the IOTA participant misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the data sharing agreement, CMS may do all of the following:

(*1*) Deem the IOTA participant ineligible to retrieve the beneficiary-identifiable data under paragraph (b) of this section for any amount of time.

(*2*) Terminate the IOTA participant's participation in the IOTA Model under § 512.466.

(*3*) Subject the IOTA participant to additional sanctions and penalties available under the law.

(ii) An IOTA participant must comply with all applicable laws and the terms of the data sharing in order to retrieve beneficiary-identifiable data.

(c) ***Aggregate data.***

(1) CMS shares aggregate performance data with IOTA participants, in a form and manner to be specified by CMS, which has been de-identified in accordance with 45 CFR 164.514(b). This aggregate data includes, when available, certain de-identified data detailing the IOTA participant's performance against the transplant target information for each PY.

(2) [Reserved]

§ 512.442 Transparency requirements.

(a) ***Publication of selection criteria.***

(1) The IOTA participant must publicly post on its website the criteria used by the IOTA participant for evaluating and selecting patients for addition to their kidney transplant waitlist by the end of PY 1.

(2) For all subsequent PYs, the IOTA participant must review its publicly posted criteria used for evaluating and selecting patients for addition to its kidney transplant waitlist and ensure that the information is up to date on its website by the end of each relevant PY.

(3) IOTA participants performing living donor kidney transplants must—

(i) Publicly post on its website its living donor selection criteria for evaluating potential living donors for kidney transplant waitlist patients by the end of PY 2; and

(ii) For all subsequent PYs, review its living donor selection criteria for evaluating potential living donors for kidney transplant waitlist patients and ensure that the information on its website is correct by the end of each relevant PY.

(b) [Reserved]

(c) ***Review of acceptance criteria.*** IOTA participants must review transplant organ offer acceptance criteria (as defined at § 512.402) with their IOTA waitlist patients who are Medicare beneficiaries at least once every 6 months that the Medicare beneficiary is on their waitlist.

(1) The IOTA participant must conduct this review via patient visit, phone, email or mail on an individual basis, unless the Medicare beneficiary declines this review.

(i) Prior to reviewing transplant organ offer acceptance criteria, as defined at § 512.402, with IOTA waitlist patients who are Medicare beneficiaries, IOTA participants must give these beneficiaries an opportunity to decline this review.

(ii) If an IOTA waitlist patient who is a Medicare beneficiary declines this review, the IOTA participant must do both of the following:

(A) Record in the IOTA waitlist patient who is a Medicare beneficiary's medical record all of the following:

(*1*) The date on which this review was declined.

(*2*) The method by which this review was declined.

(B) Offer the IOTA waitlist patient who is a Medicare beneficiary the opportunity to review transplant organ offer acceptance criteria once every 6 months at which time the IOTA waitlist patient who is a Medicare beneficiary will have the opportunity to decline this review again.

(2) The IOTA participant must record in the IOTA waitlist patient who is a Medicare beneficiary's medical record all of the following:

(i) The information specified in paragraph (c) of this section was reviewed with the IOTA waitlist patient who is a Medicare beneficiary.

(ii) The date in which this review took place.

(iii) The method by which this review was delivered.

(d) ***Change in waitlist status notification.***

(1) The IOTA participant must do the following for all IOTA waitlist patients who are Medicare beneficiaries during the model performance period:

(i) Inform IOTA waitlist patients who are Medicare beneficiaries any time their status on the waitlist is changed that would impact their ability to receive an organ offer (that is, from active to inactive).

(ii) When there is a change in waitlist status, provide notifications to each IOTA waitlist patient who is a Medicare beneficiary that includes all of the following:

(A) The most recent date the IOTA waitlist patient who is a Medicare beneficiary became inactive.

(B) The reason for the change in waitlist status.

(C) That the IOTA waitlist patient who is a Medicare beneficiary cannot receive organ offers while inactive.

(D) Information on how the IOTA waitlist patient who is a Medicare beneficiary may become active on its waitlist again.

(E) How the IOTA waitlist patient who is a Medicare beneficiary may contact the IOTA participant for more information or with any questions.

(iii) The IOTA participant must provide this notification (as described in paragraph (d)(1)(i) of this section), and the information specified in paragraph (d)(1)(ii) of this section as follows:

(A) Electronically or by mail on an individual basis.

(B) Within 10 days of the IOTA waitlist patient who is a Medicare beneficiary's change in waitlist status.

(C) Annually, thereafter, for as long as the IOTA waitlist patient who is a Medicare beneficiary remains inactive (that is, 365 consecutive days).

(2) Record in the IOTA waitlist patient who is a Medicare beneficiary's medical record a copy of the notification that includes all of the following:

(i) The method by which the notification was delivered.

(ii) The date of when the notification was delivered.

(3) For IOTA waitlist patients who are Medicare beneficiaries and—

(i) ESRD patients, the IOTA participant must also notify the dialysis facility (as defined at 42 CFR 494.10) and managing clinician (as defined at § 512.310) or nephrologist.

(ii) Non-ESRD patients, the IOTA participant must also notify the referring provider or practitioner providing care to the IOTA waitlist patient who is a Medicare beneficiary.

[89 FR 96445, Dec. 4, 2024, as amended at 91 FR 32871, June 1, 2026]

BENEFICIARY PROTECTIONS AND FINANCIAL ARRANGEMENTS, BENEFICIARY INCENTIVES, AND COMPLIANCE

§ 512.450 Required beneficiary notifications.

(a) ***General.***

(1) IOTA participants must provide notice to attributed patients who are Medicare beneficiaries that they are participating in the IOTA Model.

(2) CMS provides a notification template that IOTA participants must use. The template, at minimum does all of the following:

(i) Indicates content that the IOTA participant must not change.

(ii) Indicates where the IOTA participant may insert its own content.

(iii) Includes information regarding the attributed patient's opportunity to opt-out of data sharing with IOTA participants and how they may opt out if they choose to do so.

(3) To notify attributed patients of their rights and protections and that the IOTA participant is participating in the IOTA Model, the IOTA participant must do all of the following:

(i) Prominently display informational materials in each of their office or facility locations where attributed patients receive treatment.

(ii) Include this notification in a clear manner on its public facing website.

(iii)

(A) Provide the notification described in paragraph (a) of this section to each applicable attributed patient in a paper format at their first office visit or other outpatient visit after the start of the IOTA Model; or

(B) If the applicable attributed patient has affirmatively opted out of receiving paper communication or has chosen to receive communication through electronic methods, the notification described in paragraph (a) of this section may be distributed through that agreed upon electronic method.

(b) ***Applicability of general Innovation Center model provisions.***

(1) The requirements described in § 512.120(c) do not apply to the CMS-provided materials described in paragraph (a) of this section.

(2) All other IOTA participant communications that are descriptive model materials and activities as defined under § 512.110 must meet the requirements described in § 512.120(c).

[89 FR 96445, Dec. 4, 2024, as amended at 91 FR 32872, June 1, 2026]

§ 512.452 Financial sharing arrangements and attributed patient engagement incentives.

(a) ***General.***

(1) The IOTA participant—

(i) May enter into a sharing arrangement with an IOTA collaborator to make a gainsharing payment, or to receive an alignment payment, or both; and

(ii) Must not make a gainsharing payment or receive an alignment payment except in accordance with a sharing arrangement.

(2) A sharing arrangement must comply with the provisions of this section and all other applicable laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements.

(3) The IOTA participant must develop, maintain, and use a set of written policies for selecting providers and suppliers to be IOTA collaborators.

(i) The selection criteria must include the quality of care delivered by the potential IOTA collaborator.

(ii) The selection criteria cannot be based directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among any of the following:

(A) The IOTA participant.

(B) Any IOTA collaborator.

(C) Any collaboration agent.

(D) Any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent.

(iii) The written policies must contain criteria related to, and inclusive of, the anticipated contribution to performance across the achievement domain, efficiency domain, and quality domain by the potential IOTA collaborator.

(4) The board or other governing body of the IOTA participant must have responsibility for overseeing the IOTA participant's participation in the IOTA Model, including but not limited to all of the following:

(i) Arrangements with IOTA collaborators.

(ii) Payment of gainsharing payments.

(iii) Receipt of alignment payments.

(iv) Use of beneficiary incentives in the IOTA Model.

(5) If an IOTA participant enters into a sharing arrangement, its compliance program must include oversight of sharing arrangements and compliance with the applicable requirements of the IOTA Model.

(b) ***Requirements.***

(1) A sharing arrangement must be—

(i) In writing;

(ii) Signed by the parties; and

(iii) Entered into before care is furnished to an attributed patient during the PY under the sharing arrangement.

(2) Participation in a sharing arrangement must be voluntary and without penalty for nonparticipation.

(3) Participation in the sharing arrangement must require the IOTA collaborator to comply with the requirements of this model, as those pertain to their actions and obligations.

(4) The sharing arrangement—

(i) Must set out the mutually agreeable terms for the financial arrangement between the parties to guide and reward model care redesign for future performance across the achievement domain, efficiency domain, and quality domain;

(ii) Must not reflect the results of model PYs that have already occurred; and

(iii) Where the financial outcome of the sharing arrangement terms are known before signing.

(5) The sharing arrangement must require the IOTA collaborator and its employees, contractors (including collaboration agents), and subcontractors to comply with all of the following:

(i) The applicable provisions of this part (including requirements regarding beneficiary notifications, access to records, record retention, and participation in any evaluation, monitoring, compliance, and enforcement activities performed by CMS or its designees).

(ii) All applicable Medicare provider enrollment requirements at § 424.500 of this chapter, including having a valid and active TIN or NPI, during the term of the sharing arrangement.

(iii) All other applicable laws and regulations.

(6) The sharing arrangement must require the IOTA collaborator to have or be covered by a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of the IOTA Model that apply to its role as an IOTA collaborator, including any distribution arrangements.

(7) The sharing arrangement must not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care.

(8) The written agreement memorializing a sharing arrangement must specify all of the following:

(i) The purpose and scope of the sharing arrangement.

(ii) The identities and obligations of the parties, including specified IOTA activities and other services to be performed by the parties under the sharing arrangement.

(iii) The date of the sharing arrangement.

(iv) Management and staffing information, including type of personnel or contractors that would be primarily responsible for carrying out IOTA activities.

(v) The financial or economic terms for payment, including all of the following:

(A) Eligibility criteria for a gainsharing payment.

(B) Eligibility criteria for an alignment payment.

(C) Frequency of gainsharing or alignment payment.

(D) Methodology and accounting formula for determining the amount of a gainsharing payment that is substantially based on performance across the achievement domain, efficiency domain and quality domain, and the provision of IOTA activities.

(E) Methodology and accounting formula for determining the amount of an alignment payment.

(9) The sharing arrangement must not—

(i) Induce—

(A) The IOTA participant;

(B) The IOTA collaborator; or

(C) Any employees, contractors, or subcontractors of the IOTA participant or IOTA collaborator to reduce or limit medically necessary services to any attributed patient; or

(ii) Restrict the ability of an IOTA collaborator to make decisions in the best interests of its patients, including the selection of devices, supplies, and treatments.

(c) ***Gainsharing payments and alignment payments.***

(1) Gainsharing payments, if any, must meet all of the following:

(i) Be derived solely from upside risk payments.

(ii) Be distributed on an annual basis (not more than once per performance year).

(iii) Not be a loan, advance payment, or payment for referrals or other business.

(iv) Be clearly identified as a gainsharing payment at the time it is paid.

(2) To be eligible to receive a gainsharing payment an IOTA collaborator must contribute to performance across the achievement domain, efficiency domain or quality domain for the PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment. The contribution to performance across the achievement domain, efficiency domain, or quality domain criteria must be established by the IOTA participant and directly related to the care of attributed patients.

(3) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment:

(i) An IOTA collaborator other than PGP, NPPGP, or TGP must have directly furnished a billable item or service to an attributed patient that occurred in the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment or incurred a downside risk payment.

(ii) An IOTA collaborator that is a PGP, NPPGP, or TGP must meet the following criteria:

(A) The PGP, NPPGP, or TGP must have billed for an item or service that was rendered by one or more PGP member, NPPGP member, or TGP member respectively to an attributed patient that occurred during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment or incurred a downside risk payment.

(B) The PGP, NPPGP, or TGP must have contributed to IOTA activities and been clinically involved in the care of attributed patients during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment or incurred a downside risk payment.

(4) The total amount of a gainsharing payment for a PY paid to an IOTA collaborator that is a physician or nonphysician practitioner must not exceed 50 percent of the Medicare-approved amounts under the PFS for items and services billed by that physician or nonphysician practitioner to the IOTA participant's attributed patients during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment being made.

(5) The total amount of a gainsharing payment for a PY paid to an IOTA collaborator that is a PGP, NPPGP, or TGP must not exceed 50 percent of the Medicare-approved amounts under the PFS for items and services billed by that PGP, NPPGP, or TGP and furnished to the IOTA participant's attributed patients by the PGP members, NPPGP members, or TGP members respectively during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment being made.

(6) The amount of any gainsharing payments must be determined in accordance with a methodology that is substantially based on contribution to the performance across the achievement domain, efficiency domain or quality domain and the provision of IOTA activities. The methodology may take into account the amount of such IOTA activities provided by an IOTA collaborator relative to other IOTA collaborators.

(7) For a PY, the aggregate amount of all gainsharing payments that are derived from the upside risk payment the IOTA participant receives from CMS must not exceed the amount of that upside risk payment.

(8) No entity or individual, whether a party to a sharing arrangement or not, may condition the opportunity to make or receive gainsharing payments or to make or receive alignment payments directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the IOTA participant, any IOTA collaborator, any collaboration agent, or any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent.

(9) An IOTA participant must not make a gainsharing payment to an IOTA collaborator that is subject to any action for noncompliance with this part, or the fraud and abuse laws, or for the provision of substandard care to attributed patients or other integrity problems.

(10) The sharing arrangement must require the IOTA participant to recoup any gainsharing payment that contained funds derived from a CMS overpayment on an upside risk payment or was based on the submission of false or fraudulent data.

(11) Alignment payments from an IOTA collaborator to an IOTA participant may be made at any interval that is agreed upon by both parties, and must not be—

(i) Issued, distributed, or paid prior to the calculation by CMS of a payment amount reflected in the notification of the downside risk payment;

(ii) Loans, advance payments, or payments for referrals or other business; or

(iii) Assessed by an IOTA participant if the IOTA participant does not owe a downside risk payment.

(12) The IOTA participant must not receive any amounts under a sharing arrangement from an IOTA collaborator that are not alignment payments.

(13) For a PY, the aggregate amount of all alignment payments received by the IOTA participant must not exceed 50 percent of the IOTA participant's downside risk payment amount.

(14) The aggregate amount of all alignment payments from a single IOTA collaborator to the IOTA participant may not be greater than 25 percent of the IOTA participant's downside risk payment over the course of a single PY for an IOTA collaborator.

(15) The amount of any alignment payments must be determined in accordance with a methodology that does not directly account for the volume or value of referrals or business otherwise generated by, between or among the IOTA participant, any IOTA collaborator, any collaboration agent, or any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent.

(16) All gainsharing payments and any alignment payments must be administered by the IOTA participant in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book).

(17) All gainsharing payments and alignment payments must be made by check, EFT, or another traceable cash transaction.

(d) ***Documentation requirements.***

(1) The IOTA participant must do all of the following:

(i) Document the sharing arrangement contemporaneously with the establishment of the arrangement.

(ii) Maintain accurate current and historical lists of all IOTA collaborators, including IOTA collaborator names and addresses. With respect to these lists the IOTA participant must—

(A) Update such lists on at least a quarterly basis; and

(B) On a web page on the IOTA participant's website, the IOTA participant must—

(*1*) Publicly report the current and historical lists of IOTA collaborators; and

(*2*) Include any written policies for selecting individuals and entities to be IOTA collaborators required by the IOTA participant.

(iii) Maintain and require each IOTA collaborator to maintain contemporaneous documentation with respect to the payment or receipt of any gainsharing payment or alignment payment that includes at a minimum all of the following:

(A) Nature of the payment (gainsharing payment or alignment payment).

(B) Identity of the parties making and receiving the payment.

(C) Date of the payment.

(D) Amount of the payment.

(E) Date and amount of any recoupment of all or a portion of an IOTA collaborator's gainsharing payment.

(F) Explanation for each recoupment, such as whether the IOTA collaborator received a gainsharing payment that contained funds derived from a CMS overpayment of an upside risk payment or was based on the submission of false or fraudulent data.

(2) The IOTA participant must keep records of all of the following:

(i) Its process for determining and verifying its potential and current IOTA collaborators' eligibility to participate in Medicare.

(ii) A description of current health information technology, including systems to track upside risk payments and downside risk payments.

(iii) Its plan to track gainsharing payments and alignment payments.

(3) The IOTA participant must retain and provide access to, and must require each IOTA collaborator to retain and provide access to, the required documentation in accordance with §§ 512.460 and 1001.952(ii).

§ 512.454 Distribution arrangements.

(a) ***General.***

(1) An IOTA collaborator may distribute all or a portion of any gainsharing payment it receives from the IOTA participant only in accordance with a distribution arrangement, as defined at § 512.402.

(2) All distribution arrangements must comply with the provisions of this section and all other applicable laws and regulations, including the fraud and abuse laws.

(b) ***Requirements.***

(1) All distribution arrangements must be in writing and signed by the parties, contain the date of the agreement, and be entered into before care is furnished to attributed patients under the distribution arrangement.

(2) Participation in a distribution arrangement must be voluntary and without penalty for nonparticipation.

(3) The distribution arrangement must require the collaboration agent to comply with all applicable laws and regulations.

(4) The opportunity to make or receive a distribution payment must not be conditioned directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the IOTA participant, any IOTA collaborator, any collaboration agent, or any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent.

(5) The amount of any distribution payments from an NPPGP to an NPPGP member, or from a TGP to a TGP member must be determined in accordance with a methodology that is substantially based on contribution to performance across the achievement domain, efficiency domain, and quality domain and the provision of IOTA activities and that may take into account the amount of such IOTA activities provided by a collaboration agent relative to other collaboration agents.

(6) The amount of any distribution payments from a PGP must be determined either in a manner that complies with § 411.352(g) of this chapter or in accordance with a methodology that is substantially based on contribution to performance across the achievement domain, efficiency domain and quality domain and the provision of IOTA activities and that may take into account the amount of such IOTA activities provided by a collaboration agent relative to other collaboration agents.

(7) Except for a distribution payment from a PGP to a PGP member that complies with § 411.352(g) of this chapter, a collaboration agent is eligible to receive a distribution payment only if the collaboration agent furnished or billed for an item or service rendered to an attributed patient that occurred during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment being distributed.

(8) Except for a distribution payment from a PGP to a PGP member that complies with § 411.352(g) of this chapter, the total amount of distribution payments for a PY paid to a collaboration agent must not exceed 50 percent of the total Medicare-approved amounts under the PFS for items and services billed by that PGP, NPPGP or TGP for items and services furnished by PGP members, NPPGP members or TGP members respectively to attributed patients that occurred during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment being distributed.

(9) With respect to the distribution of any gainsharing payment received by a PGP, NPPGP, or TGP, the total amount of all distribution payments must not exceed the amount of the gainsharing payment received by the IOTA collaborator from the IOTA participant.

(10) All distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(11) The collaboration agent must retain the ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

(12) The distribution arrangement must not—

(i) Induce the collaboration agent to reduce or limit medically necessary items and services to any Medicare beneficiary; or

(ii) Reward the provision of items and services that are medically unnecessary.

(13) The IOTA collaborator must maintain contemporaneous documentation regarding distribution arrangements in accordance with § 512.454, including the following:

(i) The relevant written agreements.

(ii) The date and amount of any distribution payment(s).

(iii) The identity of each collaboration agent that received a distribution payment.

(iv) A description of the methodology and accounting formula for determining the amount of any distribution payment.

(14) The IOTA collaborator may not enter into a distribution arrangement with any collaboration agent that has a sharing arrangement with the same IOTA participant.

(15) The IOTA collaborator must retain and provide access to and must require collaboration agents to retain and provide access to, the required documentation in accordance with § 512.460.

§ 512.455 Enforcement authority.

(a) ***OIG authority.*** Nothing contained in the terms of the IOTA Model or this part limits or restricts the authority of the HHS Office of Inspector General, including its authority to audit, evaluate, investigate, or inspect the IOTA participant, IOTA collaborators, or any other person or entity or their records, data, or information, without limitation.

(b) ***Other authority.*** Nothing contained in the terms of the IOTA Model or this part limits or restricts the authority of any government agency permitted by law to audit, evaluate, investigate, or inspect the participant hospital, IOTA collaborators, or any other person or entity or their records, data, or information, without limitation.

§ 512.456 Beneficiary incentive: Part B and Part D immunosuppressive drug cost sharing support.

(a) ***Cost sharing support for Part B and Part D immunosuppressive drugs.*** For immunosuppressive drugs covered under Medicare Part B or Medicare Part D and prescribed to an attributed patient, the IOTA participant may subsidize, in whole or in part, the cost sharing associated with the immunosuppressive drugs under Part B and Part D immunosuppressive drug cost sharing support defined at § 512.402 if all of the following conditions are met:

(1) The attributed patient is an eligible attributed patient as defined at § 512.402.

(2) The IOTA participant must provide a written policy in a form and manner specified by CMS for the provision of Part B and Part D immunosuppressive drug cost sharing support that is approved by CMS before the PY in which the cost sharing support is made available.

(i) The IOTA participant must revalidate the written policy with CMS and in a form and manner specified by CMS for the provision of Part B and Part D immunosuppressive drug cost sharing support before its provision in a subsequent PY.

(ii) The IOTA participant's initial written policy and the revalidation of the written policy must establish and justify the criteria that qualify an eligible attributed patient to receive Part B and Part D immunosuppressive drug cost sharing support.

(iii) The IOTA participant's written policy and the revalidation of the written policy must include an attestation that the IOTA participant will not, in providing Part B and Part D immunosuppressive drug cost sharing support, take into consideration the type, cost, generic status, or manufacturer of the immunosuppressive drug(s) or limit an eligible attributed patients' choice of pharmacy.

(b) ***Restrictions.***

(1) An IOTA participant must not take into consideration the type, cost, generic status, or manufacturer of the immunosuppressive drug(s) or limit an eligible attributed patients' choice of pharmacy when providing Part B and Part D immunosuppressive drug cost sharing support.

(2) An IOTA participant may not receive financial or operational support for Part B and Part D immunosuppressive drug cost sharing support from pharmacies and pharmaceutical manufacturers.

(c) ***Documentation.***

(1) An IOTA participant must maintain contemporaneous documentation that includes all of the following:

(i) The identity of the eligible attributed patient to whom Part B and Part D immunosuppressive drug cost sharing support was provided.

(ii) The date or dates on which Part B and Part D immunosuppressive drug cost sharing support was provided.

(iii) The amount or amounts of Part B and Part B immunosuppressive drug cost sharing support that was provided.

(2) An IOTA participant must retain and make available records pertaining to Part B and Part D immunosuppressive drug cost sharing support to the Federal Government in accordance with § 512.460.

§ 512.458 Attributed patient engagement incentives.

(a) ***General.*** An IOTA participant may choose to provide any or all of the following types of attributed patient engagement incentives to an attributed patient under the conditions described in paragraph (b) of this section:

(1) Communication devices and related communication services directly pertaining to communication with an IOTA participant or IOTA collaborator to improve communication between an attributed patient and an IOTA participant or IOTA collaborator.

(2) Transportation to and from an IOTA participant and between other providers and suppliers involved in the provision of ESRD care.

(3) Mental health services to address an attributed patient's behavioral health symptoms pre- and post-transplant.

(4) In-home care to support the health of the attributed patient or the kidney transplant in the post-transplant period.

(b) ***Conditions.*** An IOTA participant may provide attributed patient engagement incentives of the type described in paragraphs (a)(1) through (4) of this section when all of the following conditions are met:

(1) An IOTA participant provides a written policy, in a form and manner specified by CMS, for the provision of attributed patient engagement incentives.

(2) CMS approves an IOTA participants written policy before the first PY in which an attributed patient engagement incentive is first made available.

(3) CMS revalidates the IOTA participant's written policy in a form and manner specified by CMS prior to each PY in which an attributed patient engagement incentive is offered subsequently.

(4) The IOTA participant includes in its written policy:

(i) A description of the items or services that will be provided as attributed patient engagement incentives.

(ii) An explanation of how each item or service that will be an attributed patient engagement incentive has a reasonable connection to any of the following:

(A) An attributed patient achieving and maintaining active status on a kidney transplant waitlist.

(B) An attributed patient accessing the kidney transplant procedure.

(C) The health of the attributed patient or the kidney transplant in the post-transplant period.

(D) A justification for the need for the attributed patient engagement incentives that is specific to the IOTA participant's attributed patient population.

(iii) An attestation that items that are attributed patient engagement incentives will be provided directly to an attributed patient.

(iv) An attestation that the IOTA participant will pay service providers directly for services that are attributed patient engagement incentives.

(v) An attestation that any items or services acquired by the IOTA participant that will be furnished as attributed patient engagement incentives will be acquired for the minimum amount necessary for an attributed patient to achieve the goals described in paragraphs (3)(ii)(A) through (C) of this paragraph.

(c) ***Restrictions.***

(1) An IOTA participant must provide items that are attributed patient engagement incentives directly to an attributed patient.

(2) An IOTA participant must pay service providers directly for any services that are offered as attributed patient engagement incentive.

(3) An IOTA participant must not offer an attributed patient engagement incentive that is tied to the receipt of items or services from a particular provider or supplier.

(4) An IOTA participant must not advertise or promote an item or service that is an attributed patient engagement incentive, except to make an attributed patient aware of the availability of the items or services at the time an attributed patient could reasonably benefit from them.

(5) An IOTA participant must not receive donations directly or indirectly to purchase attributed patient engagement incentives.

(6) An IOTA participant must retrieve items that that are attributed patient engagement incentives from the attributed patient when the attributed patient is no longer eligible for the that item or at the conclusion of the IOTA Model, whichever is earlier.

(i) Documented, diligent, good faith attempts to retrieve items that are attributed patient engagement incentives are deemed to meet the retrieval requirement.

(ii) [Reserved]

(7) Items that are communication devices:

(i) May not exceed $1,000 in retail value for any one attributed patient in any one PY;

(ii) Must remain the property of the IOTA participant;

(iii) Must be retrieved from the attributed patient by the IOTA participant—

(A) When the attributed patient is no longer eligible for the communication device or at the conclusion of the IOTA Model, whichever is earlier; and

(B) Before another communication device may be made available to the same attributed patient.

(d) ***Documentation.*** The IOTA participant must do all of the following:

(1) Maintain contemporaneous documentation of items and services furnished as attributed patient engagement incentives that includes, at minimum all of the following:

(i) The date the attributed patient engagement incentive is provided.

(ii) The identity of the attributed patient to whom the item or service was provided.

(2) Document all retrieval attempts of items that are attributed patient engagement incentives, including the ultimate date of retrieval.

(3)

(i) Retain records pertaining to furnished attributed patient engagement incentives.

(ii) Make the records available to the Federal Government in accordance with § 512.460.

§ 512.459 Application of the CMS-sponsored model arrangements and patient incentives safe harbor.

(a) ***Application of the CMS-sponsored model arrangements safe harbor.*** CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)(1)) is available to protect remuneration furnished in the IOTA Model in the form of the Sharing Arrangement's gainsharing payments, the Sharing Arrangement's alignment payments, and the Distribution Arrangement's distribution payments that meet all safe harbor requirements set forth in 42 CFR 1001.952(ii), 512.452, and 512.454.

(b) ***Application of the CMS-sponsored model patient incentives safe harbor.*** CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(2)) is available to protect remuneration furnished in the IOTA Model in the form of Part B and Part D immunosuppressive drug cost sharing support and the attributed patient engagement incentives that meet all safe harbor requirements set forth in 42 CFR 1001.952(ii), 512.456 and 512.458.

§ 512.460 Audit rights and records retention.

(a) ***Right to audit.*** The Federal Government, including CMS, HHS, and the Comptroller General, or their designees, has the right to audit, inspect, investigate, and evaluate any documents and other evidence regarding implementation of the IOTA Model.

(b) ***Access to records.*** The IOTA participant and its IOTA collaborators must maintain and give the Federal Government, including, but not limited to, CMS, HHS, and the Comptroller General, or their designees, access to all such documents (including books, contracts, and records) and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the implementation of the IOTA Model, including without limitation, documents, and other evidence regarding all of the following:

(1) Compliance by the IOTA participant and its IOTA collaborators with the terms of the IOTA Model.

(2) The accuracy of model-specific payments made under the IOTA Model.

(3) The IOTA participant's downside risk payments owed to CMS under the IOTA Model.

(4) Quality measure information and the quality of services performed under the terms of the IOTA Model.

(5) Utilization of items and services furnished under the IOTA Model.

(6) The ability of the IOTA participant to bear the risk of potential losses and to repay any losses to CMS, as applicable.

(7) Contemporaneous documentation of cost sharing support furnished under Part B and Part D immunosuppressive drug cost sharing support that includes the following:

(i) The identity of the eligible attributed patient to whom Part B and Part D immunosuppressive drug cost sharing support was provided.

(ii) The date or dates on which Part B and Part D immunosuppressive drug cost sharing support was provided.

(iii) The amount or amounts of the cost sharing support provided to the attributed patient.

(8) Contemporaneous documentation of items and services furnished as attributed patient engagement incentives in accordance with § 512.458 that includes all of the following, at minimum:

(i) The date the attributed patient engagement incentive is provided.

(ii) The identity of the attributed patient to whom the item or service was provided.

(9) Patient safety.

(10) Any other program integrity issues.

(c) ***Record retention.***

(1) The IOTA participant and its IOTA collaborators must maintain the documents and other evidence described in paragraph (b) of this section and other evidence for a period of 6 years from the last payment determination for the IOTA participant under the IOTA Model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the IOTA participant at least 30 days before the normal disposition date; or

(ii) There has been a termination, dispute, or allegation of fraud or similar fault against the IOTA participant or its IOTA collaborators, in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

(2)

(i) If CMS notifies the IOTA participant of the special need to retain a record or group of records in accordance with paragraph (c)(1)(i) of this section, the IOTA participant must maintain the records for such period of time as determined by CMS.

(ii) If CMS notifies the IOTA participant of a special need to retain records in accordance with paragraph (c)(1)(ii) of this section, the IOTA participant must notify its IOTA collaborators of this need to retain records for the additional period specified by CMS.

§ 512.462 Compliance and monitoring.

(a) ***Compliance with laws.*** The IOTA participant must comply with all applicable laws and regulations.

(b) ***CMS monitoring activities.***

(1) CMS, or its approved designee, may conduct monitoring activities to ensure compliance by the IOTA participant and IOTA collaborators with the terms of the IOTA Model under this subpart to—

(i) Understand IOTA participants' use of model-specific payments; and

(ii) Promote the safety of attributed patients and the integrity of the IOTA Model.

(2) Monitoring activities may include, without limitation, all of the following:

(i) Documentation requests sent to the IOTA participant and its IOTA collaborators, including surveys and questionnaires.

(ii) Audits of claims data, quality measures, medical records, and other data from the IOTA participant and its IOTA collaborators.

(iii) Interviews with the IOTA participant, including leadership personnel, medical staff, other associates, and its IOTA collaborators.

(iv) Interviews with attributed patients and their caregivers.

(v) Site visits to the IOTA participant and its IOTA collaborators, performed in a manner consistent with paragraph (c) of this section.

(vi) Monitoring quality outcomes and attributed patient data.

(vii) Tracking beneficiary complaints and appeals.

(viii) Monitoring the definition of and justification for the subpopulation of the IOTA participant's eligible attributed patients that may receive Part B and Part D immunosuppressive drug cost sharing support in accordance with § 512.456.

(ix) Monitoring the provision of attributed patient engagement incentives provided in accordance with § 512.458.

(x) Monitoring out of sequence allocation of kidneys by—

(A) Assessing the frequency at which IOTA waitlist patients, top-ranked on an IOTA participant's kidney transplant waitlist, receive the organ that was initially offered to them; and

(B) Determining the reasons behind cases where IOTA waitlist patients identified in paragraph (b)(x)(A) of this section, did not receive the kidney offered to them.

(xi) Monitoring the publication of selection criteria provision in accordance with § 512.442(a).

(xii) Monitoring the review of acceptance criteria provision in accordance with § 512.442(c).

(xiii) Monitoring the change in waitlist status provision in accordance with § 512.442(d).

(3) In conducting monitoring and oversight activities, CMS or its designees may use any relevant data or information including without limitation all Medicare claims submitted for items or services furnished to IOTA transplant patients or IOTA waitlist patients or both.

(c) ***Site visits.***

(1) The IOTA participant must cooperate in periodic site visits performed by CMS or its designees in order to facilitate the evaluation of the IOTA Model in accordance with section 1115A(b)(4) of the ACT and the monitoring of the IOTA participant's compliance with the terms of the IOTA Model, including this subpart.

(2) When scheduling the site visit, CMS or its designee provides, to the extent practicable, the IOTA participant with no less than 15 days advance notice of any site visit. CMS—

(i) Attempts, to the extent practicable, to accommodate a request for particular dates in scheduling site visits; and

(ii) Does not accept a date request from the IOTA participant that is more than 60 days after the date of the initial site visit notice from CMS.

(3) The IOTA participant must ensure that personnel with the appropriate responsibilities and knowledge associated with the purpose of the site visit are available during all site visits.

(4) CMS may perform unannounced site visits at the office of the IOTA participant at any time to investigate concerns about the health or safety of attributed patients or other program integrity issues.

(5) Nothing in this part may be construed to limit or otherwise prevent CMS from performing site visits permitted or required by applicable law.

(d) ***Reopening of payment determinations.***

(1) CMS may reopen an IOTA Model-specific payment determination on its own motion or at the request of the IOTA participant, within 4 years from the date of the determination, for good cause (as defined at § 405.986 of this chapter) except if there exists reliable evidence that the determination was procured by fraud or similar fault as defined at § 405.902 of this chapter. In the case of fraud or similar fault, CMS may reopen an IOTA Model specific payment determination at any time.

(2) CMS' decision regarding whether to reopen a model-specific payment determination is binding and not subject to appeal.

[89 FR 96445, Dec. 4, 2024, as amended at 91 FR 32872, June 1, 2026]

§ 512.464 Remedial action.

(a) ***Grounds for remedial action.*** CMS may impose one or more remedial actions described in paragraph (b) of this section if CMS determines that:

(1) The IOTA participant has failed to furnish 11 or more kidney transplants for patients aged 18 years or older, regardless of payer, during a PY or any baseline years.

(2) The IOTA participant or its IOTA collaborator has failed to comply with any of the terms of the IOTA Model, including this subpart.

(3) The IOTA participant has failed to comply with transparency requirements described at § 512.442.

(4) The IOTA participant or its IOTA collaborator has failed to comply with any applicable Medicare program requirement, rule, or regulation.

(5) The IOTA participant or its IOTA collaborator has taken any action that threatens the health or safety of an attributed patient.

(6) The IOTA participant or its IOTA collaborator has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the IOTA Model.

(7) The IOTA participant or its IOTA collaborator has undergone a change in control that presents a program integrity risk.

(8) The IOTA participant or its IOTA collaborator is subject to any sanctions of an accrediting organization or a Federal, State, or local government agency.

(9) The IOTA participant or its IOTA collaborator is subject to investigation or action by HHS (including the HHS Office of Inspector General or CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including any of the following:

(i) Being subject to the filing of a complaint or filing of a criminal charge.

(ii) Being subject to an indictment.

(iii) Being named as a defendant in a False Claims Act qui tam matter in which the Federal Government has intervened, or similar action.

(10) The IOTA participant or its IOTA collaborator has failed to demonstrate improved performance following any remedial action imposed under this section.

(11) The IOTA participant has misused or disclosed beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the applicable data sharing agreement.

(b) ***Remedial actions.*** If CMS determines that one or more grounds for remedial action described in paragraph (a) of this section has taken place, CMS may take one or more of the following remedial actions:

(1) Notify the IOTA participant and, if appropriate, require the IOTA participant to notify its IOTA collaborators of the violation.

(2) Require the IOTA participant to provide additional information to CMS or its designees.

(3) Subject the IOTA participant to additional monitoring, auditing, or both.

(4) Prohibit the IOTA participant from distributing model-specific payments, as applicable.

(5) Require the IOTA participant to terminate, immediately or by a deadline specified by CMS, its sharing arrangement with an IOTA collaborator with respect to the IOTA Model.

(6) Terminate the IOTA participant from the IOTA Model.

(7) Suspend or terminate the ability of the IOTA participant to provide Part B and Part D immunosuppressive drug cost sharing support in accordance with § 512.456 or attributed patient engagement incentives in accordance with § 512.458.

(8) Require the IOTA participant to submit a corrective action plan in a form and manner and by a deadline specified by CMS.

(9) Discontinue the provision of data sharing and reports to the IOTA participant.

(10) Recoup model-specific payments.

(11) Reduce or eliminate a model-specific payment otherwise owed to the IOTA participant.

(12) [Reserved]

(13) Any other action as may be permitted under the terms of this part.

§ 512.466 Termination.

(a) ***Termination of IOTA participant from the IOTA Model by CMS.*** CMS may immediately or with advance notice terminate an IOTA participant from participation in the model if CMS does any of the following:

(1) Determines that it no longer has the funds to support the IOTA Model.

(2) Modifies or terminates the IOTA Model in accordance with section 1115A(b)(3)(B) of the Act.

(3) Determines that the IOTA participant has done any of the following:

(i) Failed to comply with any model requirements or any other Medicare program requirement, rule, or regulation.

(ii) Failed to comply with a monitoring or auditing plan or both.

(iii) Failed to submit, obtain approval for, implement or fully comply with the terms of a corrective action plan.

(iv) Failed to demonstrate improved performance following any remedial action.

(v) Taken any action that threatens the health or safety of a Medicare beneficiary or other patient.

(vi) Submitted false data or made false representations, warranties, or certifications in connection with any aspect of the IOTA Model.

(vii) Undergoes a change in control.

(viii) Assigns or purports to assign any of the rights or obligations under the IOTA Model, voluntarily or involuntarily, whether by merger, consolidation, dissolution, operation of law, or any other manner, without the written consent of CMS.

(ix) Poses significant program integrity risks, including but not limited to any of the following:

(A) Is subject to sanctions or other actions of an accrediting organization or a Federal, State, or local government agency.

(B) Is subject to investigation or action by HHS (including OIG and CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including any of the following:

(*1*) Being subject to the filing of a complaint or filing of a criminal charge.

(*2*) Being subject to an indictment.

(*3*) Being named as a defendant in a False Claims Act qui tam matter in which the government has intervened, or similar action.

(C) If HHS or the OPTN has determined that an IOTA participant has violated the OPTN's policies, OPTN's Management and Membership policies, or HHS regulations (42 CFR part 121) upon a review conducted under 42 CFR 121.10.

(b) ***Termination of Model participation by IOTA participant.*** The IOTA participant may not terminate their participation in the IOTA Model.

(c) ***Financial settlement upon termination.*** If CMS terminates the IOTA participant's participation in the IOTA Model, CMS calculates the final performance score and any upside risk payment or downside risk payment, if applicable, for the entire PY in which the IOTA participant's participation in the model was terminated.

(1) If CMS terminates the IOTA participant's participation in the IOTA Model, CMS determines the IOTA participant's effective date of termination.

(2) If CMS terminates the IOTA participant for any reasons listed under § 512.466:

(i) CMS does not make any payments of upside risk payment for the PY in which the IOTA participant was terminated; and

(ii) The IOTA participant will remain liable for payment of any downside risk payment up to and including the PY in which termination becomes effective.

(d) ***Termination of the IOTA Model by CMS.***

(1) The general provisions for the Innovation Center model termination by CMS listed under § 512.165 apply to the IOTA Model.

(i) CMS may terminate the IOTA Model for reasons including, but not limited to, those set forth in § 512.165(a).

(ii) If CMS terminates the IOTA Model, CMS provides written notice to IOTA participants specifying the grounds for model termination and the effective date of such termination.

(2) In accordance with section 1115A(d)(2) of the Act and § 512.170(e), termination of the IOTA Model under section 1115A(b)(3)(B) of the Act is not subject to administrative or judicial review.

(3) If CMS terminates the IOTA Model, the financial settlement terms described in paragraph (c) of this section apply.

[89 FR 96445, Dec. 4, 2024, as amended at 91 FR 32873, June 1, 2026]

§ 512.468 Bankruptcy and other notifications.

(a) ***Notice of bankruptcy.***

(1) If the IOTA participant has filed a bankruptcy petition, whether voluntary or involuntary, the IOTA participant must provide written notice of the bankruptcy to CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed, unless final payment has been made by either CMS or the IOTA participant under the terms of each model tested under section 1115A of the Act in which the IOTA participant is participating or has participated and all administrative or judicial review proceedings relating to any payments under such models have been fully and finally resolved.

(2) The notice of bankruptcy must meet all of the following:

(i) Be sent by certified mail no later than 5 days after the petition has been filed.

(ii) Contain—

(A) A copy of the filed bankruptcy petition (including its docket number); and

(B) A list of all models tested under section 1115A of the Act in which the IOTA participant is participating or has participated.

(b) ***Change in control.***

(1) The IOTA participant must provide written notice to CMS at least 90 days before the effective date of any change in control.

(2) CMS may terminate an IOTA participant from the IOTA Model under § 512.466 if the IOTA participant undergoes a change in control.

(c) ***Prohibition on assignment.***

(1) Unless CMS provides prior written consent, an IOTA participant must not transfer, including by merger (whether the IOTA participant is the surviving or disappearing entity), consolidation, dissolution, or otherwise any—

(i) Discretion granted it under the model;

(ii) Right that it has to satisfy a condition under the model;

(iii) Remedy that it has under the model; or

(iv) Obligation imposed on it under the model.

(2) The IOTA participant must provide CMS 90 days advance written notice of any such proposed transfer.

(3) This obligation remains in effect after the expiration or termination of the model, or the IOTA participant's participation in the model, and until final payment by the IOTA participant under the model has been made.

(4) CMS may condition its consent to such transfer on full or partial reconciliation of upside risk payments and downside risk payments.

(5) Any purported transfer in violation of this requirement is voidable at the discretion of CMS.

WAIVERS

§ 512.470 Waivers.

CMS waives the requirements of sections 1881(b), 1833(a), 1833(b), and 1851(i)(2) of the Act, and 42 CFR 422.322(c) only to the extent necessary to make the payments under the IOTA Model described in this subpart.

[89 FR 96445, Dec. 4, 2024, as amended at 91 FR 32873, June 1, 2026]

Subpart E—Transforming Episode Accountability Model (TEAM)

Source: 89 FR 69914, Aug. 28, 2024, unless otherwise noted.

GENERAL

§ 512.500 Basis and scope of subpart.

(a) ***Basis.*** This subpart implements the test of the Transforming Episode Accountability Model (TEAM) under section 1115A(b) of the Act. Except as specifically noted in this part, the regulations under this subpart do not affect the applicability of other provisions affecting providers and suppliers under Medicare FFS, including the applicability of provisions regarding payment, coverage, and program integrity.

(b) ***Scope.*** This subpart sets forth the following:

(1) Participation in TEAM.

(2) Scope of episodes being tested.

(3) Pricing methodology.

(4) Quality measures and quality reporting requirements.

(5) Reconciliation and review processes.

(6) Data sharing and other requirements

(7) Financial arrangements and beneficiary incentives.

(8) Medicare program waivers

(9) Beneficiary protections.

(10) Cooperation in model evaluation and monitoring.

(11) Audits and record retention.

(12) Rights in data and intellectual property.

(13) Monitoring and compliance.

(14) Remedial action.

(15) Limitations on review.

(16) Miscellaneous provisions on bankruptcy and other notifications.

(17) Model termination by CMS.

(18) [Reserved]

[89 FR 69914, Aug. 28, 2024, as amended at 90 FR 37203, Aug. 4, 2025]

§ 512.505 Definitions.

For the purposes of this part, the following definitions are applicable unless otherwise stated:

AAPM stands for Advanced Alternative Payment Model.

AAPM option means the advanced alternative payment model option of TEAM for Track 2 and Track 3 TEAM participants that provide their CMS EHR Certification ID and attest to their use of CEHRT in accordance with § 512.522.

ACO means an accountable care organization, as defined at § 425.20 of this chapter.

ACO participant has the meaning set forth in § 425.20 of this chapter.

ACO provider/supplier has the meaning set forth in § 425.20 of this chapter.

Acute care hospital means a provider subject to the prospective payment system specified in § 412.1(a)(1) of this chapter.

Age bracket risk adjustment factor means the coefficient of risk associated with a patient's age bracket, calculated as described in § 512.545(a)(1).

Aggregated reconciliation target price refers to the sum of the reconciliation target prices for all episodes attributed to a given TEAM participant for a given performance year.

Alignment payment means a payment from a TEAM collaborator to a TEAM participant under a sharing arrangement, for the sole purpose of sharing the TEAM participant's responsibility for making repayments to Medicare.

AMI stands for acute myocardial infarction

Anchor hospitalization means the initial hospital stay upon admission for an episode category included in TEAM, as described in § 512.525(c), for which the institutional claim is billed through the inpatient prospective payment system (IPPS).

Anchor procedure means a procedure related to an episode category, as described in § 512.525(c), included in TEAM that is permitted and paid for by Medicare when performed in a hospital outpatient department (HOPD) and billed through the Hospital Outpatient Prospective Payment System (OPPS).

APC stands for Ambulatory Payment Classification.

APM stands for Alternative Payment Model.

APM Entity means an entity as defined in § 414.1305 of this chapter.

Baseline episode spending refers to total episode spending by all providers and suppliers associated with a given MS-DRG/HCPCS episode type for all hospitals in a given region during the baseline period.

Baseline period means the 3-year historical period used to construct the preliminary target price and reconciliation target price for a given performance year.

Baseline year means any one of the 3 years included in the baseline period.

Benchmark price means average standardized episode spending by all providers and suppliers associated with a given MS-DRG/HCPCS episode type for all hospitals in a given region during the applicable baseline period.

Beneficiary means an individual who is enrolled in Medicare FFS.

Beneficiary who is dually eligible means a beneficiary enrolled in both Medicare and full Medicaid benefits.

BPCI stands for Bundled Payments for Care Improvement, which was an episode_based payment initiative with four models tested by the CMS Innovation Center from April 2013 to September 2018.

BPCI Advanced stands for the Bundled Payments for Care Improvement Advanced Model, which is an episode-based payment model tested by the CMS Innovation Center from October 2018 to December 2025.

CABG (Coronary Artery Bypass Graft Surgery) means any coronary revascularization procedure paid through the IPPS under MS-DRGs 231-236, including both elective CABG and CABG procedures performed during initial acute myocardial infarction (AMI) treatment.

CCN stands for CMS certification number.

CDI stands for the Community Deprivation Index.

CEHRT means certified electronic health record technology that meets the requirements set forth in § 414.1305 of this chapter.

Change in control means any of the following:

(1) The acquisition by any "person" (as this term is used in sections 13(d) and 14(d) of the Securities Exchange Act of 1934) of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Securities Exchange Act of 1934), directly or indirectly, of voting securities of the TEAM participant representing more than 50 percent of the TEAM participant's outstanding voting securities or rights to acquire such securities.

(2) The acquisition of the TEAM participant by any individual or entity.

(3) The sale, lease, exchange, or other transfer (in one transaction or a series of transactions) of all or substantially all of the assets of the TEAM participant.

(4) The approval and completion of a plan of liquidation of the TEAM participant, or an agreement for the sale or liquidation of the TEAM participant.

CJR stands for the Comprehensive Care for Joint Replacement Model, which is an episode-based payment model tested by the CMS Innovation Center from April 2016 to December 2024.

Clinician engagement list means the list of eligible clinicians or MIPS eligible clinicians that participate in TEAM activities and have a contractual relationship with the TEAM participant, and who are not listed on the financial arrangements list, as described in § 512.522(c).

CMS Electronic Health Record (EHR) Certification ID means the identification number that represents the combination of Certified Health Information Technology that is owned and used by providers and hospitals to provide care to their patients and is generated by the Certified Health Information Technology Product List.

Collaboration agent means an individual or entity that is not a TEAM collaborator and that is either of the following:

(1) A member of a PGP, NPPGP, or TGP that has entered into a distribution arrangement with the same PGP, NPPGP, or TGP in which he or she is an owner or employee, and where the PGP, NPPGP, or TGP is a TEAM collaborator.

(2) An ACO participant or ACO provider/supplier that has entered into a distribution arrangement with the same ACO in which it is participating, and where the ACO is a TEAM collaborator.

Composite quality score (CQS) means a score computed for each TEAM participant to summarize the TEAM participant's level of quality performance and improvement on specified quality measures as described in § 512.547.

Core-based statistical area (CBSA) means a statistical geographic entity defined by the Office of Management and Budget (OMB) consisting of the county or counties associated with at least one core (urbanized area or urban cluster) of at least 10,000 population, plus adjacent counties having a high degree of social and economic integration with the core as measured through commuting ties with the counties containing the core.

CORF stands for comprehensive outpatient rehabilitation facility.

Covered services means the scope of health care benefits described in sections 1812 and 1832 of the Act for which payment is available under Part A or Part B of Title XVIII of the Act.

Critical access hospital (CAH) means a hospital designated under subpart F of part 485 of this chapter.

CQS adjustment amount means the amount subtracted from the positive or negative reconciliation amount to generate the reconciliation payment or repayment amount.

CQS adjustment percentage means the percentage CMS applies to the positive or negative reconciliation amount based on the TEAM participant's CQS performance.

CQS baseline period means the time period used to benchmark quality measure performance.

Days means calendar days.

Descriptive TEAM materials and activities means general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, web pages, mailings, social media, or other materials or activities distributed or conducted by or on behalf of the TEAM participant or its downstream participants when used to educate, notify, or contact beneficiaries regarding TEAM. All of the following communications are not descriptive TEAM materials and activities:

(1) Communications that do not directly or indirectly reference TEAM (for example, information about care coordination generally).

(2) Information on specific medical conditions.

(3) Referrals for health care items and services, except as required by § 512.564.

(4) Any other materials that are excepted from the definition of “marketing” as that term is defined at 45 CFR 164.501.

Discount factor means a set percentage included in the preliminary target price and reconciliation target price intended to reflect Medicare's potential savings from TEAM.

Distribution arrangement means a financial arrangement between a TEAM collaborator that is an ACO, PGP, NPPGP, or TGP and a collaboration agent for the sole purpose of distributing some or all of a gainsharing payment received by the ACO, PGP, NPPGP, or TGP.

Distribution payment means a payment from a TEAM collaborator that is an ACO, PGP, NPPGP, or TGP to a collaboration agent, under a distribution arrangement, composed only of gainsharing payments.

DME stands for durable medical equipment.

Downstream collaboration agent means an individual who is not a TEAM collaborator or a collaboration agent and who is a member of a PGP, NPPGP, or TGP that has entered into a downstream distribution arrangement with the same PGP, NPPGP, or TGP in which he or she is an owner or employee, and where the PGP, NPPGP, or TGP is a collaboration agent.

Downstream distribution arrangement means a financial arrangement between a collaboration agent that is both a PGP, NPPGP, or TGP and an ACO participant and a downstream collaboration agent for the sole purpose of sharing a distribution payment received by the PGP, NPPGP, or TGP.

Downstream participant means an individual or entity that has entered into a written arrangement with a TEAM participant, TEAM collaborator, collaboration agent, or downstream collaboration agent under which the downstream participant engages in one or more TEAM activities.

EHR stands for electronic health record.

Eligible clinician means a clinician as defined in § 414.1305 of this chapter.

Episode category means one of the five episodes tested in TEAM as described at § 512.525(d).

Episode means all Medicare Part A and B items and services described in § 512.525(e) (and excluding the items and services described in § 512.525(f)) that are furnished to a beneficiary described in § 512.535 during the time period that begins on the date of the beneficiary's admission to an anchor hospitalization or the date of the anchor procedure, as described at § 512.525(c), and ends on the 30th day following the date of discharge from the anchor hospitalization or anchor procedure, with the date of discharge or date of the anchor procedure itself being counted as the first day in the 30-day post-discharge period, as described at § 512.537. If an anchor hospitalization is initiated on the same day as or in the 3 days following an outpatient procedure that could initiate an anchor procedure for the same episode category, the outpatient procedure initiates an anchor hospitalization and the anchor hospitalization start date is that of the outpatient procedure.

Essential access community hospital means a hospital as defined under § 412.109 of this chapter.

Final normalization factor refers to the mean of the benchmark price for each MS-DRG/HCPCS episode type and region divided by the mean of the risk-adjusted benchmark price for the same MS-DRG/HCPCS episode type and region.

Financial arrangements list means the list of eligible clinicians or MIPS eligible clinicians that have a financial arrangement with the TEAM participant, TEAM collaborator, collaboration agent, and downstream collaboration agent, as described in § 512.522(b).

Gainsharing payment means a payment from a TEAM participant to a TEAM collaborator, under a sharing arrangement, composed of only reconciliation payments, internal cost savings, or both.

HCPCS stands for Healthcare Common Procedure Coding System, which is used to bill for items and services.

Health disparities mean preventable differences in the burden of disease, injury, violence, or opportunities to achieve optimal health, health quality, or health outcomes that are experienced by one or more underserved communities within the TEAM participant's population of TEAM beneficiaries that the TEAM participant will aim to reduce.

Health-related social need means an unmet, adverse social condition that can contribute to poor health outcomes and is a result of underlying social determinants of health, which refer to the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.

HHA means a Medicare-enrolled home health agency.

High-cost outlier cap refers to the 99th percentile of regional spending for a given MS-DRG/HCPCS episode type, region, and baseline year, which is the amount at which episode spending would be capped for purposes of determining baseline and performance year episode spending.

Hospital means a hospital as defined in section 1886(d)(1)(B) of the Act.

Hospital discharge planning means the standards set forth in § 482.43 of this chapter.

ICD-CM stands for International Classification of Diseases, Clinical Modification.

Internal cost savings means the measurable, actual, and verifiable cost savings realized by the TEAM participant resulting from care redesign undertaken by the TEAM participant in connection with providing items and services to TEAM beneficiaries within an episode. Internal cost savings does not include savings realized by any individual or entity that is not the TEAM participant.

IPF stands for inpatient psychiatric facility.

IPPS stands for Inpatient Prospective Payment System, which is the payment system for subsection (d) hospitals as defined in section 1886(d)(1)(B) of the Act.

IRF stands for inpatient rehabilitation facility.

LIS stands for Medicare Part D Low-Income Subsidy.

Lower-Extremity Joint Replacement (LEJR) means any hip, knee, or ankle replacement that is paid under MS-DRG 469, 470, 521, or 522 through the IPPS or HCPCS code 27447, 27130, or 27702 through the OPPS.

LTCH stands for long-term care hospital.

Major Bowel Procedure means any small or large bowel procedure paid through the IPPS under MS-DRG 329-331.

Mandatory CBSA means a core-based statistical area selected by CMS in accordance with § 512.515 where all eligible hospitals are required to participate in TEAM.

MDC stands for Major Diagnostic Category.

Medically necessary means reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body member.

Medicare ID means the hospital CCN in the PECOS.

Medicare Severity Diagnosis-Related Group (MS-DRG) means, for the purposes of this model, the classification of inpatient hospital discharges updated in accordance with § 412.10 of this chapter.

Medicare-dependent, small rural hospital (MDH) means a specific type of hospital that meets the classification criteria specified under § 412.108 of this chapter.

Member of the NPPGP or *NPPGP member* means a nonphysician practitioner or therapist who is an owner or employee of an NPPGP and who has reassigned to the NPPGP his or her right to receive Medicare payment.

Member of the PGP or *PGP member* means a physician, nonphysician practitioner, or therapist who is an owner or employee of the PGP and who has reassigned to the PGP his or her right to receive Medicare payment.

Member of the TGP or *TGP member* means a therapist who is an owner or employee of a TGP and who has reassigned to the TGP his or her right to receive Medicare payment.

MIPS stands for Merit-based Incentive Payment System.

MIPS eligible clinician means a clinician as defined in § 414.1305 of this chapter.

Model performance period means the 60-month period from January 1, 2026, to December 31, 2030, during which TEAM is being tested and the TEAM participant is held accountable for spending and quality.

Model start date means January 1, 2026, the start of the model performance period.

MS-DRG/HCPCS episode type refers to the subset of episodes within an episode category that are associated with a given MS-DRG/HCPCS, as set forth at § 512.540(a)(1).

Non-AAPM option means the option of TEAM for TEAM participants in Track 1 or for TEAM participants in Track 2 or Track 3 that do not attest to use of CEHRT as described in § 512.522.

Nonphysician practitioner means one of the following:

(1) A physician assistant who satisfies the qualifications set forth at § 410.74(a)(2)(i) and (ii) of this chapter.

(2) A nurse practitioner who satisfies the qualifications set forth at § 410.75(b) of this chapter.

(3) A clinical nurse specialist who satisfies the qualifications set forth at § 410.76(b) of this chapter.

(4) A certified registered nurse anesthetist (as defined at § 410.69(b) of this chapter).

(5) A clinical social worker (as defined at § 410.73(a) of this chapter).

(6) A registered dietician or nutrition professional (as defined at § 410.134 of this chapter).

NPI stands for National Provider Identifier.

NPPGP stands for Non-Physician Provider Group Practice, which means an entity that is enrolled in Medicare as a group practice, includes at least one owner or employee who is a nonphysician practitioner, does not include a physician owner or employee, and has a valid and active TIN.

NPRA stands for Net Payment Reconciliation Amount, which means the dollar amount representing the difference between the reconciliation target price and performance year spending, after adjustments for quality and stop-gain/stop-loss limits, but prior to the post-episode spending adjustment.

OIG stands for the Department of Health and Human Services Office of the Inspector General.

OP means an outpatient procedure for which the institutional claim is billed by the hospital through the OPPS.

OPPS stands for the Outpatient Prospective Payment System.

PAC stands for post-acute care.

PBPM stands for per-beneficiary-per-month.

PECOS stands for the Provider Enrollment, Chain, and Ownership System.

Performance year means a 12-month period beginning on January 1 and ending on December 31 of each year during the model performance period.

Performance year spending means the sum of standardized Medicare claims payments during the performance year for the items and services that are included in the episode in accordance with § 512.525(e), excluding the items and services described in § 512.525(f).

PGP stands for physician group practice.

Physician has the meaning set forth in section 1861(r) of the Act.

Post-episode spending amount means the sum of all Medicare Parts A and B payments for items and services furnished to a beneficiary within 30 days after the end of an episode and includes the prorated portion of services that began during the episode and extended into the 30-day post-episode period.

Preliminary target price refers to the target price provided to the TEAM participant prior to the start of the performance year, which is subject to adjustment at reconciliation, as set forth at § 512.540.

Primary care services has the meaning set forth in section 1842(i)(4) of the Act.

Prospective normalization factor refers to the multiplier incorporated into the preliminary target price to ensure that the average of the total risk-adjusted benchmark price does not exceed the average of the total non-risk adjusted benchmark price, calculated as set forth in § 512.540(b)(6).

Prospective trend factor refers to the multiplier incorporated into the preliminary target price to estimate changes in spending patterns between the baseline period and the performance year, calculated as set forth in § 512.540(b)(7).

Provider means a "provider of services" as defined under section 1861(u) of the Act and codified in the definition of "provider" at § 400.202 of this chapter.

Provider of outpatient therapy services means an entity that is enrolled in Medicare as a provider of therapy services and furnishes one or more of the following:

(1) Outpatient physical therapy services as defined in § 410.60 of this chapter.

(2) Outpatient occupational therapy services as defined in § 410.59 of this chapter.

(3) Outpatient speech-language pathology services as defined in § 410.62 of this chapter.

QP stands for Qualifying APM Participant as defined in § 414.1305 of this chapter.

Quality-adjusted reconciliation amount refers to the dollar amount representing the difference between the reconciliation target price and performance year spending, after adjustments for quality, but prior to application of stop-gain/stop-loss limits and the post-episode spending adjustment.

Raw quality measure score means the quality measure value as obtained from the Hospital Inpatient Quality Reporting Program and the Hospital-Acquired Condition Reduction Program.

Reconciliation amount means the dollar amount representing the difference between the reconciliation target price and performance year spending, prior to adjustments for quality, stop-gain/stop-loss limits, and post-episode spending.

Reconciliation payment amount means the amount that CMS may owe to a TEAM participant after reconciliation as determined in accordance with § 512.550(g).

Reconciliation target price means the target price applied to an episode at reconciliation, as determined in accordance with § 512.545.

Region means one of the nine U.S. census divisions, as defined by the U.S. Census Bureau, with the U.S. territories included in Census Division 9.

Reorganization event refers to a merger, consolidation, spin off or other restructuring that results in a new hospital entity under a given CCN.

Repayment amount means the amount that the TEAM participant may owe to Medicare after reconciliation as determined in accordance with § 512.550(g).

Retrospective trend factor refers to the multiplier incorporated into the reconciliation target price to estimate realized changes in spending patterns during the performance year, calculated as set forth in § 512.545(f).

Rural hospital means an IPPS hospital that meets one of the following criteria:

(1) Is located in a rural area as defined under § 412.64 of this chapter.

(2) Is located in a rural census tract defined under § 412.103(a)(1) of this chapter.

Safety Net hospital means an IPPS hospital that meets at least one of the following criteria:

(1) Exceeds the 75th percentile of the proportion of Medicare beneficiaries considered dually eligible for Medicare and Medicaid across all PPS acute care hospitals in the baseline period.

(2) Exceeds the 75th percentile of the proportion of Medicare beneficiaries partially or fully eligible to receive Part D low-income subsidies across all PPS acute care hospitals in the baseline period.

Scaled quality measure score means the score equal to the percentile to which the TEAM participant's raw quality measure score would have belonged in the CQS baseline period.

Scaling factor means the ratio of the remapped MS-DRG or HCPCS/APC relative weight in the performance year, as applicable, to the original MS-DRG or HCPCS/APC relative weight in the baseline period.

Sharing arrangement means a financial arrangement between a TEAM participant and a TEAM collaborator for the sole purpose of making gainsharing payments or alignment payments under TEAM.

SNF stands for skilled nursing facility.

Sole community hospital (SCH) means a hospital that meets the classification criteria specified in § 412.92 of this chapter.

Spinal Fusion means any cervical, thoracic, or lumbar spinal fusion procedure paid through the IPPS under MS-DRG 402, 426, 427, 428, 429, 430, 447, 448, 450, 451, 471, 472, or 473, or through the OPPS under HCPCS codes 22551, 22554, 22612, 22630, or 22633.

Supplier means a supplier as defined in section 1861(d) of the Act and codified at § 400.202 of this chapter.

Surgical Hip and Femur Fracture Treatment (SHFFT) means a hip fixation procedure, with or without fracture reduction, but excluding joint replacement, that is paid through the IPPS under MS-DRGs 480-482.

TAA stands for total ankle arthroplasty.

TEAM activities mean any activity related to promoting accountability for the quality, cost, and overall care for TEAM beneficiaries and performance in the model, including managing and coordinating care; encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery; or carrying out any other obligation or duty under the model.

TEAM beneficiary means a beneficiary who meets the beneficiary inclusion criteria in § 512.535 and who is in an episode.

TEAM collaborator means an ACO or one of the following Medicare-enrolled individuals or entities that enters into a sharing arrangement:

(1) SNF.

(2) HHA.

(3) LTCH.

(4) IRF.

(5) Physician.

(6) Nonphysician practitioner.

(7) Therapist in private practice.

(8) CORF.

(9) Provider of outpatient therapy services.

(10) PGP.

(11) Hospital.

(12) CAH.

(13) NPPGP.

(14) Therapy Group Practice (TGP).

TEAM data sharing agreement means an agreement entered into between the TEAM participant and CMS that includes the terms and conditions for any beneficiary-identifiable data shared with the TEAM participant under § 512.562.

TEAM HCC count refers to the TEAM Hierarchical Condition Category count, which is a categorical risk adjustment variable designed to reflect a beneficiary's overall health status during a lookback period by grouping similar diagnoses into one related category and counting the total number of diagnostic categories that apply to the beneficiary.

TEAM participant means an acute care hospital that either—

(1) Initiates episodes and is paid under the IPPS and OPPS with a CCN primary address located in one of the mandatory CBSAs selected for participation in TEAM in accordance with § 512.515; or

(2) Makes a voluntary opt-in participation election to participate in TEAM in accordance with § 512.510 and is accepted to participate in TEAM by CMS.

TEAM payment means a payment made by CMS only to TEAM participants, or a payment adjustment made only to payments made to TEAM participants, under the terms of TEAM that is not applicable to any other providers or suppliers.

TEAM reconciliation report means the report prepared after each reconciliation that CMS provides to the TEAM participant notifying the TEAM participant of the outcome of the reconciliation.

TGP or therapy group practice means an entity that is enrolled in Medicare as a therapy group in private practice, includes at least one owner or employee who is a therapist in private practice, does not include an owner or employee who is a physician or nonphysician practitioner, and has a valid and active TIN.

THA means total hip arthroplasty.

Therapist means one of the following individuals as defined at § 484.4 of this chapter:

(1) Physical therapist.

(2) Occupational therapist.

(3) Speech-language pathologist.

Therapist in private practice means a therapist that—

(1) Complies with the special provisions for physical therapists in private practice in § 410.60(c) of this chapter;

(2) Complies with the special provisions for occupational therapists in private practice in § 410.59(c) of this chapter; or

(3) Complies with the special provisions for speech-language pathologists in private practice in § 410.62(c) of this chapter.

TIN stands for taxpayer identification number.

TKA stands for total knee arthroplasty.

Track 1 means a participation track in TEAM in which any TEAM participant may participate for the first performance year and only TEAM participants who are a safety net hospital, as defined in § 512.505, may participate for performance years 1 through 3 of the model. TEAM participants in Track 1 are subject to all of the following:

(1) CQS adjustment percentage described in § 512.550(d)(1)(i).

(2) Limitations on gain described in § 512.550(e)(2).

(3) The calculation of the reconciliation payment described in § 512.550(g).

Track 2 means a participation track in TEAM in which certain TEAM participants, as described in § 512.520(b)(4), may request to participate in for performance years 2 through 5. TEAM participants in Track 2 are subject to all of the following:

(1) CQS adjustment percentage described in § 512.550(d)(1)(ii).

(2) Limitations on gain and loss described in § 512.550(e)(2) and § 512.550(e)(3).

(3) The calculation of the reconciliation payment or repayment amount described in § 512.550(g).

Track 3 means a participation track in TEAM in which a TEAM participant may participate in for performance years 1 through 5. TEAM participants in Track 3 are subject to all of the following:

(1) CQS adjustment percentage described in § 512.550(d)(1)(iii).

(2) Limitations on loss and gain described in § 512.550(e)(1) and in § 512.550(e)(2).

(3) The calculation of the reconciliation payment or repayment amount described in § 512.550(g).

Trend year means either of the 2 years immediately prior to the 3-year baseline period used in combination with the baseline period to calculate the prospective trend factor.

U.S. Territories means American Samoa, the Federated States of Micronesia, Guam, the Marshall Islands, and the Commonwealth of the Northern Mariana Islands, Palau, Puerto Rico, U.S. Minor Outlying Islands, and the U.S. Virgin Islands.

Weighted scaled score means the scaled quality measure score multiplied by its normalized weight.

[89 FR 69914, Aug. 28, 2024, as amended at 90 FR 37203, Aug. 4, 2025]

TEAM Participation

§ 512.508 Mandatory participation.

(a) ***General.*** TEAM participants, as defined in § 512.505, must participate in TEAM for the full duration of the model performance period, unless CMS terminates TEAM or the TEAM participant receives notice of termination from TEAM in accordance with § 512.596.

(b) ***New hospital exception.*** New hospitals with a Medicare ID with an initial effective date after December 31, 2024, within the PECOS that initiate episodes and are paid under the IPPS and OPPS with a CCN primary address located in one of the mandatory CBSAs selected for participation in TEAM in accordance with § 512.515, must participate in TEAM at the beginning of the performance year that follows one full performance year since their Medicare ID initial effective date.

(1) As described in § 512.550(b)(2)(ii), CMS performs reconciliation calculations for any new or surviving TEAM participant that results from a TEAM participant's reorganization event, as defined in § 512.505, for episodes where the anchor hospitalization admission or anchor procedure occurred on or after the effective date of the reorganization event. Therefore, new hospitals that result from a TEAM participant's reorganization event begin participation in TEAM on the effective date of the reorganization event.

(2) [Reserved]

(c) ***Newly qualifying hospital exception.***

(1) Hospitals that begin to satisfy the definition of TEAM participant, as described in § 512.505, must participate in TEAM at the beginning of the performance year that follows one full performance year since the date on which they began to satisfy the definition of TEAM participant.

(2) Hospitals that no longer satisfy the definition of TEAM participant, as described in § 512.505, end TEAM participation on the date they no longer satisfy the definition.

(i) CMS notifies hospitals identified in this paragraph (c)(2) within 30 days of the hospital no longer satisfying the TEAM participant definition or as soon as is reasonably practicable.

(ii) [Reserved]

(d) ***Monitoring.*** CMS may monitor specifically for the potential shifting of patients with high anticipated treatment costs from TEAM participants to new non-participant hospitals, including hospitals in the participation deferment period in accordance with § 512.505(b) and (c).

[90 FR 37204, Aug. 4, 2025]

§ 512.510 Voluntary opt-in participation.

(a) ***General.*** Hospitals that wish to voluntarily opt-in to TEAM for the full duration of the model performance period must submit a written participation election letter as described in paragraph (d) of this section during the voluntary participation election period specified in paragraph (c) of this section.

(b) ***Eligibility.*** A hospital must not be located in a mandatory CBSA selected for TEAM participation, in accordance with § 512.515, and must satisfy one of the following criteria to be eligible for voluntary opt-in participation election—

(1) Be a participant hospital in the CJR model that participates in CJR until the last day of the last performance year, December 31, 2024; or

(2) Be a hospital participating in the BPCI Advanced model, either as a participant or downstream episode initiator, that participates in BPCI Advanced until the last day of the last performance period, December 31, 2025.

(c) ***Voluntary participation election period.*** The voluntary participation election period begins on January 1, 2025 and ends on January 31, 2025.

(d) ***Voluntary participation election letter.*** The voluntary participation election letter serves as the model participation agreement. CMS may accept the voluntary participation election letter if the letter meets all of the following criteria:

(1) Includes all of the following:

(i) Hospital name.

(ii) Hospital address.

(iii) Hospital CCN.

(iv) Hospital contact name, telephone number, and email address.

(v) Model name (TEAM).

(2) Includes a certification that the hospital will—

(i) Comply with all applicable requirements of this part and all other laws and regulations applicable to its participation in TEAM; and

(ii) Submit data or information to CMS that is accurate, complete and truthful, including, but not limited to, the participation election letter and any other data or information that CMS uses for purposes of TEAM.

(3) Is signed by the hospital administrator, chief financial officer, or chief executive officer with authority to bind the hospital.

(4) Is submitted in the form and manner specified by CMS.

(e) ***CMS rejection of participation letter.*** CMS may reject a participation election letter for reasons including, but not limited to, program integrity concerns or ineligibility, and notifies the hospital of the rejection within 30 days of the determination.

§ 512.515 Geographic areas.

(a) ***General.*** CMS uses stratified random sampling to select the mandatory CBSAs included in TEAM.

(b) ***Exclusions.*** CMS excludes from the selection of geographic areas CBSAs that meet any of the following criteria:

(1) Are located entirely in the State of Maryland.

(2) Are located partially in Maryland, and in which more than 50 percent of the five episode categories tested in TEAM were initiated at a Maryland hospital between January 1, 2022 and June 30, 2023.

(3) Did not have at least one episode for at least one of the five episode categories tested in TEAM between January 1, 2022 and June 30, 2023.

(c) ***Stratification.***

(1) Based on the median for each of the following four metrics, CMS designates the CBSAs that are not excluded in accordance with paragraph (b) of this section as “high” and “low”:

(i) Average episode spend for a broad set of episode categories tested in the BPCI Advanced Model, as described in § 512.505, between January 1, 2022 and June 30, 2023.

(ii) Number of acute care hospitals paid under the IPPS between January 1, 2022 and June 30, 2023.

(iii) Past exposure to CMS' bundled payment models, which are Bundled Payments for Care Improvement (BPCI) Models 2, 3, and 4, as described in § 512.505, Comprehensive Care for Joint Replacement (CJR) as described in § 512.505, or BPCI Advanced between October 1, 2013 and December 31, 2022.

(iv) Number of Safety Net hospitals in 2022 that have initiated at least one episode between January 1, 2022 and June 30, 2023 for at least one of the five episode categories tested in TEAM.

(2)

(i) CMS stratifies the CBSAs into mutually exclusive groups corresponding to the 16 unique combinations of these “high” and “low” designations.

(ii) CMS assigns selection probabilities ranging from 20 percent to 33.3 percent to each of the 16 strata, with a higher selection probability for strata containing CBSAs with a high number of safety net hospitals or low past exposure to bundles and a lower selection probability for all other strata.

(3)

(i) CMS recategorizes outlier CBSAs in these 16 strata with a very high number of safety net hospitals into a 17th stratum.

(ii) CMS assigns a selection probability of 50 percent to the 17th stratum.

(4)

(i) CMS recategorizes CBSAs still remaining in the first 16 strata with at least one hospital participating in BPCI Advanced or CJR as of January 1, 2024 or those located in the states of Vermont, Connecticut, or Hawaii into an 18th stratum.

(ii) CMS assigns a selection probability of 20 percent to the 18th stratum.

(d) ***Random selection into TEAM.*** CMS randomly selects mandatory CBSAs into TEAM from each of the 18 strata according to selection probabilities described in paragraph (c) of this section.

§ 512.520 Participation tracks.

(a) ***For performance year 1:***

(1) Any TEAM participant may choose to participate in Track 1 or Track 3.

(2) The TEAM participant must notify CMS of its track choice, prior to performance year 1, in a form and manner and by a date specified by CMS.

(3) CMS assigns the TEAM participant to Track 1 for performance year 1 if a TEAM participant does not choose a track in the form and manner and by the date specified by CMS.

(b) ***For performance years 2 through 5:***

(1) CMS assigns a TEAM participant to participate in Track 3 unless the TEAM participant requests to participate in Track 1 or Track 2 and receives approval from CMS to participate in Track 1 or Track 2, with the exception that a TEAM participant cannot request participation in Track 1 for performance years 4 and 5.

(2) The TEAM participant must notify CMS of its Track 1 or Track 2 request prior to performance year 2, and prior to every performance year thereafter, as applicable, in a form and manner and by a date specified by CMS.

(3) CMS does not approve a TEAM participant's request to participate in Track 1 submitted in accordance with paragraph (b)(2) of this section unless the TEAM participant is a safety net hospital, as defined in § 512.505, at the time of the request.

(4) CMS does not approve a TEAM participant's request to participate in Track 2 submitted in accordance with paragraph (b)(2) of this section unless the TEAM participant is one of the following hospital types at the time of the request:

(i) Medicare-dependent hospital (as defined in § 512.505) and the Medicare Dependent Hospital program, as authorized by statute, is not expired at the time Track 2 selections are due, as described in paragraph (b)(2) of this section.

(ii) Rural hospital (as defined in § 512.505).

(iii) Safety Net hospital (as defined in § 512.505).

(iv) Sole community hospital (as defined in § 512.505).

(v) Essential access community hospital (as defined in § 512.505).

(5) A TEAM participant who does not notify CMS of its Track 1 or Track 2 request prior to a given performance year in the form and manner and by the date specified by CMS or who is not a safety net hospital, as defined as defined in § 512.505, or one of the hospital types specified in paragraph (b)(4) of this section at the time of the request is assigned to Track 3 for the applicable performance year.

[89 FR 69914, Aug. 28, 2024, as amended at 90 FR 37204, Aug. 4, 2025]

§ 512.522 APM options.

(a) ***TEAM APM options.*** For performance years 1 through 5, a TEAM participant may choose either of the following options based on their CEHRT use and track participation:

(1) ***AAPM option.*** A TEAM participant participating in Track 2 or Track 3 may select the AAPM option by attesting in a form and manner and by a date specified by CMS to their use of CEHRT, as defined in § 414.1305 of this chapter, on an annual basis prior to the start of each performance year.

(i) A TEAM participant that selects the AAPM option as provided for in paragraph (a)(1) must provide their CMS electronic health record certification ID in a form and manner and by a date specified by CMS on annual basis prior to the end of each performance year.

(ii) A TEAM participant that selects the AAPM option as provided for in paragraph (a)(1) must retain documentation of their attestation to CEHRT use and provide access to the documentation in accordance with § 512.586.

(2) ***Non-AAPM option.*** CMS assigns the TEAM participant to the non-AAPM option if the TEAM participant is in Track 1 or if the TEAM participant is in Track 2 or Track 3 and does not attest in a form and manner and by a date specified by CMS to their use of CEHRT as defined in § 414.1305 of this chapter.

(b) ***Financial arrangements list.*** A TEAM participant with TEAM collaborators, collaboration agents, or downstream collaboration agents during a performance year must submit to CMS a financial arrangements list in a form and manner and by a date specified by CMS on a quarterly basis for each performance year. The financial arrangements list must include the following:

(1) ***TEAM collaborators.*** For each physician, nonphysician practitioner, or therapist who is a TEAM collaborator during the performance year:

(i) The name, TIN, and NPI of the TEAM collaborator.

(ii) The start date and, if applicable, end date, for the sharing arrangement between the TEAM participant and the TEAM collaborator.

(2) ***Collaboration agents.*** For each physician, nonphysician practitioner, or therapist who is a collaboration agent during the performance year:

(i) The name, TIN, and NPI of the collaboration agent and the name and TIN of the TEAM collaborator with which the collaboration agent has entered into a distribution arrangement.

(ii) The start date and, if applicable, end date, for the distribution arrangement between the TEAM collaborator and the collaboration agent.

(3) ***Downstream collaboration agents.*** For each physician, nonphysician practitioner, or therapist who is a downstream collaboration agent during the performance year:

(i) The name, TIN, and NPI of the downstream collaboration agent and the name and TIN of the collaboration agent with which the downstream collaboration agent has entered into a downstream distribution arrangement.

(ii) The start date and, if applicable, end date, for the downstream distribution arrangement between the collaboration agent and the downstream collaboration agent.

(c) ***Clinician engagement list.*** A TEAM participant must submit to CMS a clinician engagement list in a form and manner and by a date specified by CMS on a quarterly basis during each performance year. The clinician engagement list must include the following:

(1) For each physician, nonphysician practitioner, or therapist who is not on a TEAM participant's financial arrangements list during the performance year but who does have a contractual relationship with the TEAM participant and participates in TEAM activities during the performance year:

(i) The name, TIN, and NPI of the physician, nonphysician practitioner, or therapist.

(ii) The start date and, if applicable, the end date for the contractual relationship between the physician, nonphysician practitioner, or therapist and the TEAM participant.

(d) ***Attestation to no individuals.*** A TEAM participant with no individuals that meet the criteria specified in paragraphs (b)(1) through (3) of this section for the financial arrangements list or paragraph (c) of this section for the clinician engagement list must attest in a form and manner and by a date specified by CMS that there are no financial arrangements or clinician engagements to report.

(e) ***Documentation requirements.*** A TEAM participant that submits a financial arrangements list specified in paragraph (b) of this section or a clinician engagement list specified in paragraph (c) of this section must retain and provide access to the documentation in accordance with § 512.586.

SCOPE OF EPISODES BEING TESTED

§ 512.525 Episodes.

(a) ***Time periods.*** All episodes must begin on or after January 1, 2026 and end on or before December 31, 2030.

(b) ***Episode attribution.*** All items and services included in the episode are attributed to the TEAM participant at which the anchor hospitalization or anchor procedure, as applicable, occurs.

(c) ***Episode initiation.*** An episode is initiated by—

(1) A beneficiary's admission to a TEAM participant for an anchor hospitalization that is paid under a MS-DRG specified in paragraph (d) of this section; or

(2) A beneficiary's receipt of an anchor procedure billed under a HCPCS code specified in paragraph (d) of this section. If an anchor hospitalization is initiated on the same day as or in the 3 days following an outpatient procedure that could initiate an anchor procedure for the same episode category, the episode start date is that of the outpatient procedure rather than the admission date, and an anchor procedure is not initiated.

(d) ***Episode categories.*** The MS-DRGs and HCPCS codes included in the episodes are as follows:

(1) ***Lower Extremity Joint Replacement (LEJR):***

(i) IPPS discharge under MS-DRG 469, 470, 521, or 522; or

(ii) OPPS claim for HCPCS codes 27447, 27130, or 27702.

(2) ***Surgical Hip/Femur Fracture Treatment (SHFFT).*** IPPS discharge under MS-DRG 480 to 482.

(3) ***Coronary Artery Bypass Graft Surgery (CABG).*** IPPS discharge under MS-DRG 231 to 236.

(4) ***Spinal Fusion:***

(i) IPPS discharge under MS-DRG 402, 426, 427, 428, 429, 430, 447, 448, 450, 451, 471, 472, 473; or

(ii) OPPS claim for HCPCS codes 22551, 22554, 22612, 22630, or 22633.

(5) ***Major Bowel Procedure.*** IPPS discharge under MS-DRG 329 to 331.

(e) ***Included services.*** All Medicare Part A and B items and services are included in the episode, except as specified in paragraph (f) of this section. These services include, but are not limited to, the following:

(1) Physicians' services.

(2) Inpatient hospital services (including hospital readmissions).

(3) IPF services.

(4) LTCH services.

(5) IRF services.

(6) SNF services.

(7) HHA services.

(8) Hospital outpatient services.

(9) Outpatient therapy services.

(10) Clinical laboratory services.

(11) DME.

(12) Part B drugs and biologicals, except for those excluded under paragraph (f) of this section.

(13) Hospice services.

(14) Part B professional claims dated in the 3 days prior to an anchor hospitalization if a claim for the surgical procedure for the same episode category is not detected as part of the hospitalization because the procedure was performed by the TEAM participant on an outpatient basis, but the patient was subsequently admitted as an inpatient.

(f) ***Excluded services.*** The following items, services, and payments are excluded from the episode:

(1) Select items and services considered unrelated to the anchor hospitalization or the anchor procedure for episodes in the baseline period and performance year, including, but not limited to, the following:

(i) Inpatient hospital admissions for MS-DRGs that group to the following categories of diagnoses:

(A) Oncology.

(B) Trauma medical.

(C) Organ transplant.

(D) Ventricular shunt.

(ii) Inpatient hospital admissions that fall into the following Major Diagnostic Categories (MDCs):

(A) MDC 02 (Diseases and Disorders of the Eye).

(B) MDC 14 (Pregnancy, Childbirth, and Puerperium).

(C) MDC 15 (Newborns).

(D) MDC 25 (Human Immunodeficiency Virus).

(2) New technology add-on payments, as defined in part 412, subpart F of this chapter for episodes in the baseline period and performance year.

(3) Transitional pass-through payments for medical devices as defined in § 419.66 of this chapter for episodes initiated in the baseline period and performance year.

(4) Hemophilia clotting factors provided in accordance with § 412.115 of this chapter for episodes in the baseline period and performance year.

(5) Part B payments for low-volume drugs, high-cost drugs and biologicals, and blood clotting factors for hemophilia for episodes in the baseline period and performance year, billed on outpatient, carrier, and DME claims, defined as—

(i) Drug/biological HCPCS codes that are billed in fewer than 31 episodes in total across all episodes in TEAM during the baseline period;

(ii) Drug/biological HCPCS codes that are billed in at least 31 episodes in the baseline period and have a mean cost of greater than $25,000 per episode in the baseline period; and

(iii) HCPCS codes corresponding to clotting factors for hemophilia patients, identified in the quarterly average sales price file for certain Medicare Part B drugs and biologicals as HCPCS codes with clotting factor equal to 1, HCPCS codes for new hemophilia clotting factors not included in the baseline period, and other HCPCS codes identified as hemophilia.

(6) Part B payments for low-volume drugs, high-cost drugs and biologicals, and blood clotting factors for hemophilia for episodes initiated in the performance year, billed on outpatient, carrier, and DME claims, defined as—

(i) Drug/biological HCPCS codes that were not captured in the baseline period and appear in 10 or fewer episodes in the performance year;

(ii) Drug/biological HCPCS codes that were not included in the baseline period, appear in more than 10 episodes in the performance year, and have a mean cost of greater than $25,000 per episode in the performance year; and

(iii) Drug/biological HCPCS codes that were not included in the baseline period, appear in more than 10 episodes in the performance year, have a mean cost of $25,000 or less per episode in the performance year, and correspond to a drug/biological that appears in the baseline period but was assigned a new HCPCS code between the baseline period and the performance year.

(iv) HCPCS codes for new hemophilia clotting factors not included in the baseline period.

(g) ***TEAM exclusions List.*** The list of excluded MS-DRGs, MDCs, and HCPCS codes is posted on the CMS website.

(h) ***Updating the TEAM exclusions list.*** The list of excluded services is updated through rulemaking to reflect all of the following:

(1) Changes to the MS-DRGs under the IPPS.

(2) Coding changes.

(3) Other issues brought to CMS' attention.

§ 512.535 Beneficiary inclusion criteria.

(a) Episodes tested in TEAM include only those in which care is furnished to beneficiaries who meet all of the following criteria upon admission for an anchor procedure or anchor hospitalization:

(1) Are enrolled in Medicare Parts A and B.

(2) Are not eligible for Medicare on the basis of having end stage renal disease, as described in § 406.13 of this chapter.

(3) Are not enrolled in any managed care plan (for example, Medicare Advantage, health care prepayment plans, or cost-based health maintenance organizations).

(4) Are not covered under a United Mine Workers of America health care plan.

(5) Have Medicare as their primary payer.

(b) The episode is canceled in accordance with § 512.537(b) if at any time during the episode a beneficiary no longer meets all criteria in this section.

§ 512.537 Determination of the episode.

(a) ***Episode conclusion.***

(1) An episode ends on the 30th day following the date of the anchor procedure or the date of discharge from the anchor hospitalization, as applicable, with the date of the anchor procedure or the date of discharge from the anchor hospitalization being counted as the first day in the 30-day post-discharge period.

(b) ***Cancellation of an episode.*** The episode is canceled and is not included in the reconciliation calculation as specified in § 512.545 if any of the following occur:

(1) The beneficiary ceases to meet any criterion listed in § 512.535.

(2) The beneficiary dies during the anchor hospitalization or the outpatient stay for the anchor procedure.

(3) The episode qualifies for cancellation due to extreme and uncontrollable circumstances. An extreme and uncontrollable circumstance occurs if both of the following criteria are met:

(i) The TEAM participant has a CCN primary address that—

(A) Is located in an emergency area, as those terms are defined in section 1135(g) of the Act, for which the Secretary has issued a waiver under section 1135 of the Act; and

(B) Is located in a county, parish, or tribal government designated in a major disaster declaration or emergency disaster declaration under the Stafford Act.

(ii) The date of admission to the anchor hospitalization or the date of the anchor procedure is during an emergency period (as defined in section 1135(g) of the Act) or in the 30 days before the date that the emergency period (as defined in section 1135(g) of the Act) begins.

PRICING METHODOLOGY

§ 512.540 Determination of preliminary target prices.

(a) ***Preliminary target price application.*** CMS establishes preliminary target prices for TEAM participants for each performance year of the model as follows:

(1) ***MS-DRG/HCPCS episode type.*** CMS uses the MS-DRGs and, as applicable, HCPCS codes specified in § 512.525(d) when calculating the preliminary target prices for each MS-DRG/HCPCS episode type.

(i) CMS determines a separate preliminary target price for each of the 24 MS-DRGs specified in § 512.525(d).

(ii) Preliminary target prices for a subset of the MS-DRGs specified in § 512.525(d) include certain HCPCS codes as follows:

(A) HCPCS 27130 and 27447 are included in MS-DRG 470.

(B) HCPCS 27702 is included in MS-DRG 469.

(C) HCPCS 22551 and 22554 are included in MS-DRG 473.

(D) HCPCS 22612 and 22630 are included in MS-DRG 451.

(E) HCPCS 22633 is included in MS-DRG 402.

(2) ***Applicable time period for preliminary target prices.*** CMS calculates preliminary target prices for each MS-DRG/HCPCS episode type and region for each performance year and applies the preliminary target price to each episode based on the episode's date of discharge from the anchor hospitalization or the date of the anchor procedure, as applicable. CMS also does all of the following:

(i) Accounts for MS-DRG and HCPCS/APC code changes between the baseline period and performance year by identifying diagnosis or procedure codes that are being moved from one MS-DRG or HCPCS/APC to another for the relevant performance year and mapping the new or revised MS-DRG or HCPCS/APC codes to the original codes that were used in the baseline period.

(ii) Constructs preliminary target prices using the remapped MS-DRG or HCPCS/APC codes in the same manner described in paragraph (b) of this section, with target prices for each MS-DRG/HCPCS episode type, inclusive of episodes initiated by anchor hospitalizations and anchor procedures that would be related to the remapped MS-DRG or HCPCS/APC codes.

(iii) Adjusts the preliminary target price by calculating and applying the scaling factor to the standardized episode spending of the MS-DRG portion for the anchor hospitalization or standardized episode spending of the HCPCS/APC portion of the anchor procedure.

(3) ***Episodes that begin in one performance year and end in the subsequent performance year.*** CMS applies the preliminary target price to the episode based on the date of discharge from the anchor hospitalization or the date of the anchor procedure, as applicable, and reconciles the episode based on the date of discharge from the anchor hospitalization or the date of the anchor procedure.

(b) ***Preliminary target price calculation.***

(1) ***Calculation of the preliminary target price.*** CMS calculates preliminary target prices based on average baseline episode spending for the region where the TEAM participant is located.

(i) The region used for calculating the preliminary target price corresponds to the U.S. Census Division associated with the primary address of the CCN of the TEAM participant, and the regional episode spending amount is based on all hospitals in the region, except as specified in § 512.540(b)(1)(ii).

(ii) In cases where a TEAM participant is located in a mandatory CBSA selected for participation in TEAM which spans more than one region, the TEAM participant and all other hospitals in the mandatory CBSA are grouped into the region where the most populous city in the mandatory CBSA is located for pricing and payment calculations.

(2) ***Baseline periods and associated performance years.*** CMS uses the following baseline periods to determine baseline episode spending:

(i) Performance Year 1: Episodes with anchor hospitalization start dates or anchor procedure dates beginning on or after January 1, 2022, and anchor hospitalization discharge dates or anchor procedure dates between January 1, 2022, and December 31, 2024.

(ii) Performance Year 2: Episodes with anchor hospitalization or anchor procedure start dates beginning on or after January 1, 2023, and anchor hospitalization discharge dates or anchor procedure dates between January 1, 2023, and December 31, 2025.

(iii) Performance Year 3: Episodes with anchor hospitalization or anchor procedure start dates beginning on or after January 1, 2024, and anchor hospitalization discharge dates or anchor procedure dates between January 1, 2024, and December 31, 2026.

(iv) Performance Year 4: Episodes with anchor hospitalization or anchor procedure start dates beginning on or after January 1, 2025, and anchor hospitalization discharge dates or anchor procedure dates between January 1, 2025, and December 31, 2027.

(v) Performance Year 5: Episodes with anchor hospitalization or anchor procedure start dates beginning on or after January 1, 2026, and anchor hospitalization discharge dates or anchor procedure dates between January 1, 2026, and December 31, 2028.

(3) ***Baseline episode spending weights.*** CMS calculates the benchmark price as the weighted average of baseline episode spending, applying the following weights:

(i) Baseline episode spending from baseline year 1 is weighted at 17 percent.

(ii) Baseline episode spending from baseline year 2 is weighted at 33 percent.

(iii) Baseline episode spending from baseline year 3 is weighted at 50 percent.

(4) ***Exclusion for high episode spending.*** CMS applies a high-cost outlier cap to baseline episode spending at the 99th percentile of regional spending for each of the MS-DRG/HCPCS episode types specified in paragraph (a)(1)(ii) of this section for each baseline year individually.

(5) ***Exclusion of incentive programs and add-on payments under existing Medicare payment systems.*** Certain Medicare incentive programs and add-on payments are excluded from baseline episode spending by using, with certain modifications, the CMS Price (Payment) Standardization Detailed Methodology used for the Medicare spending per beneficiary measure in the Hospital Value-Based Purchasing Program.

(6) ***Prospective normalization factor.*** Based on the episodes in the most recent calendar year of the baseline period, CMS calculates a prospective normalization factor at the MS-DRG/HCPCS region level, which is a multiplier that ensures that the average of the total risk-adjusted benchmark price does not exceed the average of the total non-risk adjusted benchmark price, by doing the following:

(i) CMS applies risk adjustment multipliers, as specified in § 512.545(a)(1) through (3), to the most recent baseline year episodes to calculate the estimated risk-adjusted target price for all performance year episodes.

(ii) CMS divides the mean of the preliminary target price for each episode across all hospitals and regions by the mean of the estimated risk-adjusted target price calculated in § 512.540(b)(6)(i) for the same episode types across all hospitals and regions.

(7) ***Prospective trend factor.*** CMS calculates a multiplier for each MS-DRG/HCPCS episode type and region which is applied to the most recent calendar year of the applicable baseline period. The multiplier is calculated using linear regression on the logarithmically transformed average regional spending for each MS-DRG/HCPCS episode type in the baseline years and trend years at both the regional and national level. CMS exponentiates the coefficient from this regression to calculate the estimated annual change (where an exponentiated coefficient of 1 signifies no change) in average regional spending for each MS-DRG/HCPCS episode type from year to year. CMS then squares this value to calculate the 2-year prospective trend factor. The prospective trend factor for each MS-DRG/HCPCS episode type and region is the average (arithmetic mean) of the multiplier for that MS-DRG/HCPCS episode type and region and the national average for that MS-DRG/HCPCS episode type.

(8) ***Communication of preliminary target prices.*** CMS communicates the preliminary target prices for each MS-DRG/HCPCS episode type for each region, and the preliminary target prices for each MS-DRG/HCPCS episode type specific to the TEAM participant before the performance year in which they apply.

(c) ***Discount factor.*** CMS incorporates an episode category specific discount factor of 1.5 percent for CABG and Major Bowel episodes and 2 percent for LEJR, SHFFT, and Spinal Fusion episodes to the TEAM participant's preliminary episode target prices intended to reflect Medicare's potential savings from TEAM.

[89 FR 69914, Aug. 28, 2024, as amended at 90 FR 37204, Aug. 4, 2025]

§ 512.545 Determination of reconciliation target prices.

CMS calculates the reconciliation target price as follows:

(a) CMS risk adjusts the preliminary episode target prices computed under § 512.540 at the beneficiary level using a TEAM Hierarchical Condition Category (HCC) count risk adjustment factor, an age bracket risk adjustment factor, a beneficiary economic risk adjustment factor, and at the hospital level using a hospital bed size risk adjustment factor and a safety net hospital risk adjustment factor, and at the episode category-specific beneficiary level using factors specified in paragraphs (a)(6)(i) through (v) of this section.

(1) The TEAM HCC count risk adjustment factor uses five variables, representing beneficiaries with zero, one, two, three, or four or more CMS-HCC conditions based on a 180-day lookback period that ends on the day prior to the anchor hospitalization or anchor procedure.

(2) The age bracket risk adjustment factor uses four variables, representing beneficiaries in the following age groups as of the first day of the episode:

(i) Less than 65 years.

(ii) 65 to less than 75 years.

(iii) 75 years to less than 85 years.

(iv) 85 years or more.

(3) The beneficiary economic risk adjustment factor uses two variables, representing beneficiaries that, as of the first day of the episode—

(i) Meet one or more of the following economic measures:

(A) [Reserved]

(B) National CDI above the 80th percentile.

(C) Eligibility for the low-income subsidy.

(D) Eligibility for full Medicaid benefits.

(ii) Do not meet any of the three economic measures in paragraph (a)(3)(i) of this section.

(4) The hospital bed size risk adjustment factor uses four variables based on the TEAM participant's characteristics:

(i) 250 beds or fewer.

(ii) 251-500 beds.

(iii) 501-850 beds.

(iv) 850 beds or more.

(5) The safety net hospital risk adjustment factor is based on the TEAM participant meeting the definition of safety net hospital, as defined in § 512.505.

(6) Episode category-specific beneficiary level risk adjustment factors represent the presence or absence in beneficiaries, based on a 180-day lookback period that ends on the day prior to the anchor hospitalization or anchor procedure, of each of the following conditions:

(i) CABG episode category.

(A) Prior post-acute care use.

(B) HCC 37: Diabetes with Chronic Complications.

(C) HCC 48: Morbid Obesity.

(D) HCC 125: Dementia, Severe.

(E) HCC 126: Dementia, Moderate.

(F) HCC 127: Dementia, Mild or Unspecified.

(G) HCC 155: Major Depression, Moderate or Severe, without Psychosis.

(H) HCC 199: Parkinson and Other Degenerative Disease of Basal Ganglia.

(I) HCC 213: Cardio-Respiratory Failure and Shock.

(J) HCC 224: Acute on Chronic Heart Failure.

(K) HCC 226: Heart Failure, Except End-Stage and Acute.

(L) HCC 228: Acute Myocardial Infarction.

(M) HCC 229: Unstable Angina and Other Acute Ischemic Heart Disease.

(N) HCC 238: Specified Heart Arrhythmias.

(O) HCC 249: Ischemic or Unspecified Stroke.

(P) HCC 253: Hemiplegia/Hemiparesis.

(Q) HCC 263: Atherosclerosis of Arteries of the Extremities with Ulceration or Gangrene.

(R) HCC 280: Chronic Obstructive Pulmonary Disease, Interstitial Lung Disorders, and Other Chronic Lung Disorders.

(S) HCC 298: Severe Diabetic Eye Disease, Retinal Vein Occlusion, and Vitreous Hemorrhage.

(T) HCC 326: Chronic Kidney Disease, Stage 5.

(U) HCC 327: Chronic Kidney Disease, Severe (Stage 4).

(V) HCC 383: Chronic Ulcer of Skin, Except Pressure, Not Specified as Through to Bone or Muscle.

(W) [Reserved]

(X) HCC 409: Amputation Status, Lower Limb/Amputation Complications.

(ii) LEJR episode category.

(A) Ankle procedure or reattachment, partial hip procedure, partial knee arthroplasty, total hip arthroplasty or hip resurfacing procedure, and total knee arthroplasty.

(B) Disability as the original reason for Medicare enrollment.

(C) Prior post-acute care use.

(D) HCC 17: Cancer Metastatic to Lung, Liver, Brain, and Other Organs; Acute Myeloid Leukemia Except Promyelocytic.

(E) HCC 36: Diabetes with Severe Acute Complications.

(F) HCC 37: Diabetes with Chronic Complications.

(G) HCC 48: Morbid Obesity.

(H) HCC 125: Dementia, Severe.

(I) HCC 126: Dementia, Moderate.

(J) HCC 127: Dementia, Mild or Unspecified.

(K) HCC 151: Schizophrenia.

(L) HCC 155: Major Depression, Moderate or Severe, without Psychosis.

(M) HCC 199: Parkinson and Other Degenerative Disease of Basal Ganglia.

(N) HCC 224: Acute on Chronic Heart Failure.

(O) HCC 225: Acute Heart Failure (Excludes Acute on Chronic).

(P) HCC 226: Heart Failure, Except End-Stage and Acute.

(Q) HCC 238: Specified Heart Arrhythmias.

(R) HCC 253: Hemiplegia/Hemiparesis.

(S) HCC 267: Deep Vein Thrombosis and Pulmonary Embolism.

(T) HCC 280: Chronic Obstructive Pulmonary Disease, Interstitial Lung Disorders, and Other Chronic Lung Disorders.

(U) [Reserved]

(V) HCC 326: Chronic Kidney Disease, Stage 5.

(W) HCC 327: Chronic Kidney Disease, Severe (Stage 4).

(X) HCC 383: Chronic Ulcer of Skin, Except Pressure, Not Specified as Through to Bone or Muscle.

(Y) HCC402: Hip Fracture/Dislocation.

(iii) Major Bowel Procedure episode category.

(A) Long-term institutional care use.

(B) HCC 17: Cancer Metastatic to Lung, Liver, Brain, and Other Organs; Acute Myeloid Leukemia Except Promyelocytic.

(C) HCC 22: Bladder, Colorectal, and Other Cancers.

(D) HCC 37: Diabetes with Chronic Complications.

(E) HCC 48: Morbid Obesity.

(F) HCC 78: Intestinal Obstruction/Perforation.

(G) HCC 125: Dementia, Severe.

(H) HCC 126: Dementia, Moderate.

(I) HCC 127: Dementia, Mild or Unspecified.

(J) HCC 151: Schizophrenia.

(K) HCC 155: Major Depression, Moderate or Severe, without Psychosis.

(L) HCC 199: Parkinson and Other Degenerative Disease of Basal Ganglia.

(M) HCC 201: Seizure Disorders and Convulsions.

(N) HCC 211: Respirator Dependence/Tracheostomy Status/Complications.

(O) HCC 213: Cardio-Respiratory Failure and Shock.

(P) HCC 224: Acute on Chronic Heart Failure.

(Q) HCC 226: Heart Failure, Except End-Stage and Acute.

(R) HCC 238: Specified Heart Arrhythmias.

(S) HCC 253: Hemiplegia/Hemiparesis.

(T) HCC 267: Deep Vein Thrombosis and Pulmonary Embolism.

(U) HCC 280: Chronic Obstructive Pulmonary Disease, Interstitial Lung Disorders, and Other Chronic Lung Disorders.

(V) HCC 326: Chronic Kidney Disease, Stage 5.

(W) HCC 327: Chronic Kidney Disease, Severe (Stage 4).

(X) HCC 383: Chronic Ulcer of Skin, Except Pressure, Not Specified as Through to Bone or Muscle.

(Y) HCC 463: Artificial Openings for Feeding or Elimination.

(iv) SHFFT episode category.

(A) HCC 36: Diabetes with Severe Acute Complications.

(B) HCC 37: Diabetes with Chronic Complications.

(C) HCC 38: Diabetes with Glycemic, Unspecified, or No Complications.

(D) HCC 48: Morbid Obesity.

(E) HCC 63: Chronic Liver Failure/End-Stage Liver Disorders.

(F) HCC 93: Rheumatoid Arthritis and Other Specified Inflammatory Rheumatic Disorders.

(G) HCC 109: Acquired Hemolytic, Aplastic, and Sideroblastic Anemias.

(H) HCC 125: Dementia, Severe.

(I) HCC 126: Dementia, Moderate.

(J) HCC 127: Dementia, Mild or Unspecified.

(K) HCC 180: Quadriplegia.

(L) HCC 181: Paraplegia.

(M) HCC 191: Quadriplegic Cerebral Palsy.

(N) HCC 198: Multiple Sclerosis.

(O) HCC 199: Parkinson and Other Degenerative Disease of Basal Ganglia.

(P) HCC 211: Respirator Dependence/Tracheostomy Status/Complications.

(Q) HCC 213: Cardio-Respiratory Failure and Shock.

(R) HCC 226: Heart Failure, Except End-Stage and Acute.

(S) HCC 238: Specified Heart Arrhythmias.

(T) HCC 249: Ischemic or Unspecified Stroke.

(U) HCC 253: Hemiplegia/Hemiparesis.

(V) HCC 280: Chronic Obstructive Pulmonary Disease, Interstitial Lung Disorders, and Other Chronic Lung Disorders.

(W) HCC 326: Chronic Kidney Disease, Stage 5.

(X) HCC 383: Chronic Ulcer of Skin, Except Pressure, Not Specified as Through to Bone or Muscle.

(Y) HCC 402: Hip Fracture/Dislocation.

(v) Spinal Fusion episode category.

(A) Prior post-acute care use.

(B) HCC 17: Cancer Metastatic to Lung, Liver, Brain, and Other Organs; Acute Myeloid Leukemia Except Promyelocytic.

(C) HCC 18: Cancer Metastatic to Bone, Other and Unspecified Metastatic Cancer; Acute Leukemia Except Myeloid.

(D) HCC 37: Diabetes with Chronic Complications.

(E) HCC 48: Morbid Obesity.

(F) HCC 93: Rheumatoid Arthritis and Other Specified Inflammatory Rheumatic Disorders.

(G) HCC 125: Dementia, Severe.

(H) HCC 126: Dementia, Moderate.

(I) HCC 127: Dementia, Mild or Unspecified.

(J) HCC 155: Major Depression, Moderate or Severe, without Psychosis.

(K) HCC 180: Quadriplegia.

(L) HCC 181: Paraplegia.

(M) HCC 182: Spinal Cord Disorders/Injuries.

(N) HCC 192: Cerebral Palsy, Except Quadriplegic.

(O) HCC 193: Chronic Inflammatory Demyelinating Polyneuritis and Multifocal Motor Neuropathy.

(P) HCC 199: Parkinson and Other Degenerative Disease of Basal Ganglia.

(Q) HCC 224: Acute on Chronic Heart Failure.

(R) HCC 226: Heart Failure, Except End-Stage and Acute.

(S) HCC 238: Specified Heart Arrhythmias.

(T) HCC 249: Ischemic or Unspecified Stroke.

(U) HCC 253: Hemiplegia/Hemiparesis.

(V) HCC 254: Monoplegia, Other Paralytic Syndromes.

(W) HCC 267: Deep Vein Thrombosis and Pulmonary Embolism.

(X) HCC 326: Chronic Kidney Disease, Stage 5.

(Y) HCC 383: Chronic Ulcer of Skin, Except Pressure, Not Specified as Through to Bone or Muscle.

(Z) HCC 401: Vertebral Fractures without Spinal Cord Injury.

(b) All risk adjustment factors are computed prior to the start of the performance year via a linear regression analysis. The regression analysis is computed using 3 years of claims data as follows:

(1) For performance year 1, CMS uses claims data with dates of service dated January 1, 2022 to December 31, 2024.

(2) For performance year 2, CMS uses claims data with dates of service dated January 1, 2023 to December 31, 2025.

(3) For performance year 3, CMS uses claims data with dates of service dated January 1, 2024 to December 31, 2026.

(4) For performance year 4, CMS uses claims data with dates of service dated January 1, 2025 to December 31, 2027.

(5) For performance year 5, CMS uses claims data with dates of service dated January 1, 2026 to December 30, 2028.

(c) The annual linear regression analysis produces exponentiated coefficients to determine the anticipated marginal effect of each risk adjustment factor on episode costs. CMS transforms, or exponentiates, these coefficients, and the resulting coefficients are the beneficiary and hospital-level risk adjustment factors, specified in paragraphs (a)(1) through (6) of this section, that would be used during reconciliation for the subsequent performance year.

(d) At the time of reconciliation, the preliminary target prices computed under § 512.540 are risk adjusted by applying the applicable beneficiary level and hospital-level risk adjustment factors specific to the beneficiary in the episode, as set forth in paragraphs (a)(1) through (6) of this section.

(e) The risk-adjusted preliminary target prices are normalized at reconciliation to ensure that the average of the total risk-adjusted preliminary target price does not exceed the average of the total non-risk adjusted preliminary target price.

(1) The final normalization factor at reconciliation—

(i) Is the mean benchmark price for each MS-DRG/HCPCS episode type and region divided by the mean risk-adjusted benchmark price for the same MS-DRG/HCPCS episode type and region.

(ii) As applied, cannot exceed ±5 percent of the prospective normalization factor (as specified in § 512.540(b)(6)).

(2) CMS applies the final normalization factor to the previously calculated, beneficiary and provider level, risk-adjusted target prices specific to each region and MS-DRG/HCPCS episode type.

(f) CMS calculates a multiplier for each MS-DRG/HCPCS episode type and region which is applied during reconciliation to the most recent calendar year of the applicable baseline period. The multiplier is calculated as the average regional capped performance year episode spending for each MS-DRG/HCPCS episode type divided by the average regional capped baseline period episode spending for each MS-DRG/HCPCS episode type.

(1) The retrospective trend factor is capped so that the maximum difference cannot exceed ±3 percent of the prospective trend factor (as specified in § 512.540(b)(7)).

(2) CMS applies the capped retrospective trend factor to the previously calculated normalized, risk adjusted target prices specific to each region and MS-DRG/HCPCS episode type, as specified in paragraph (e)(2) of this section, to calculate the reconciliation target prices, which are compared to performance year spending at reconciliation, as specified in § 512.550(c).

[89 FR 69914, Aug. 28, 2024, as amended at 90 FR 37205, Aug. 4, 2025]

QUALITY MEASURES AND COMPOSITE QUALITY SCORE

§ 512.547 Quality measures, composite quality score, and display of quality measures.

(a) ***Quality measures.*** CMS calculates the quality measures used to evaluate the TEAM participant's performance using Medicare claims data or patient-reported outcomes data that TEAM participants report under the Hospital Inpatient Quality Reporting Program, the Hospital-Acquired Condition Reduction Program, and the Hospital Outpatient Quality Reporting Program. The following quality measures and CQS baseline periods are used for public reporting and for determining the TEAM participant's CQS as described in paragraph (b) of this section:

(1) For performance year 1:

(i) For all episode categories: Hybrid Hospital-Wide All-Cause Readmission Measure with Claims and Electronic Health Record Data (CMIT ID #356) with a CY 2025 CQS baseline period;

(ii) For all episode categories: CMS Patient Safety and Adverse Events Composite (CMS PSI 90) (CMIT ID #135) with a CY 2025 CQS baseline period; and

(iii) For LEJR episodes: Hospital-Level Total Hip and/or Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-Based Performance Measure (PRO-PM) (CMIT ID #1618) with a CY 2025 CQS baseline period.

(2) For performance year 2:

(i) For all episode categories: Hybrid Hospital-Wide All-Cause Readmission Measure with Claims and Electronic Health Record Data (CMIT ID #356) with a CY 2025 CQS baseline period;

(ii) For all episode categories: Hospital Harm—Falls with Injury (CMIT ID #1518) with a CY 2026 CQS baseline period;

(iii) For all episode categories: Hospital Harm—Postoperative Respiratory Failure (CMIT ID #1788) with a CY 2026 CQS baseline period;

(iv) For all episode categories: Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-Rescue) (CMIT ID #134) with a CY 2026 CQS baseline period; and

(v) For LEJR episodes: Hospital-Level Total Hip and/or Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-Based Performance Measure (PRO-PM) (CMIT ID #1618) with a CY 2025 CQS baseline period.

(3) For performance years 3 through 5:

(i) For all episode categories: Hybrid Hospital-Wide All-Cause Readmission Measure with Claims and Electronic Health Record Data (CMIT ID #356) with a CY 2025 CQS baseline period.

(ii) For all episode categories: Hospital Harm—Falls with Injury (CMIT ID #1518) with a CY 2026 CQS baseline period.

(iii) For all episode categories: Hospital Harm—Postoperative Respiratory Failure (CMIT ID #1788) with a CY 2026 CQS baseline period.

(iv) For all episode categories: Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-Rescue) (CMIT ID #134) with a CY 2026 CQS baseline period.

(v) For LEJR episodes: Hospital-Level Total Hip and/or Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-Based Performance Measure (PRO-PM) (CMIT ID #1618) with a CY 2025 CQS baseline period.

(vi) For LEJR and Spinal Fusion episodes: Information Transfer PRO-PM (CMIT ID #1797) with a CY 2027 CQS baseline period.

(b) ***Calculation of the composite quality score (CQS).***

(1) CMS converts the TEAM participant's raw quality measure score for the performance year into a scaled quality measure score by comparing the raw quality measure score to the distribution of raw quality measure score percentiles among a national cohort of hospitals, consisting of TEAM participants and hospitals not participating in TEAM, in the CQS baseline period.

(i) CMS assigns a scaled quality measure score equal to the percentile to which the TEAM Participant's raw quality measure score would have belonged in the CQS baseline period.

(A) CMS assigns the higher scaled quality measure score if the TEAM participant's raw quality measure score straddles two percentiles in the CQS baseline period.

(B) For the Hospital-Level Total Hip and/or Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-Based Performance Measure (PRO-PM) (CMIT ID #1618) and the Information Transfer PRO-PM (CMIT ID # 1797):

(1) CMS assigns a scaled quality measure score of 100 if the TEAM participant's raw quality measure score is greater than the maximum of the raw quality measure scores in the CQS baseline period.

(2) CMS assigns a scaled quality measure score of 0 if the raw quality measure score is less than the minimum of the raw quality measure scores in the baseline period.

(C) For the Hybrid Hospital-Wide All-Cause Readmission Measure with Claims and Electronic Health Record Data (CMIT ID #356) measure, the CMS Patient Safety and Adverse Events Composite (CMS PSI 90) (CMIT ID #135) measure, the Hospital Harm—Falls with Injury (CMIT ID #1518) measure, the Hospital Harm—Postoperative Respiratory Failure (CMIT ID #1788) measure, and the Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-Rescue) (CMIT ID #134) measure:

(1) CMS assigns a scaled quality measure score of 0 if the TEAM participant has a raw quality measure score greater than the maximum of the raw quality measure scores in the CQS baseline period.

(2) CMS assigns a scaled quality measure score of 100 if the TEAM participant has a raw quality score less than the minimum of the raw scores in the CQS baseline period.

(D) CMS assigns a scaled quality measure of 50 if the TEAM participant has no or an incomplete raw quality measure score for a given quality measure.

(2) CMS calculates a normalized weight for each quality measure by dividing the TEAM participant's volume of attributed episodes for a given quality measure by the total volume of all the TEAM participant's attributed episodes.

(3) CMS calculates a weighted scaled score for each quality measure by multiplying each quality measure's scaled quality measure score, computed under paragraph (b)(2) of this section, by its normalized weight, computed under paragraph (b)(3) of this section.

(4) CMS sums each quality measure's weighted scaled score, computed under paragraph (b)(4) of this section, to construct the CQS.

(c) ***Display of quality measures.*** CMS does all of the following:

(1) Displays quality measure results on the publicly available CMS website that is specific to TEAM, in a form and manner consistent with other publicly reported measures.

(2) Shares quality measures with the TEAM participant prior to display on the CMS website.

(3) Uses the following time periods to share quality measure performance:

(i) Quality measure performance in performance year 1 is reported in 2027.

(ii) Quality measure performance in performance year 2 is reported in 2028.

(iii) Quality measure performance in performance year 3 is reported in 2029.

(iv) Quality measure performance in performance year 4 is reported in 2030.

(v) Quality measure performance in performance year 5 is reported in 2031.

[89 FR 69914, Aug. 28, 2024, as amended at 90 FR 37207, Aug. 4, 2025]

Reconciliation and Review Process

§ 512.550 Reconciliation process and determination of the reconciliation payment or repayment amount.

(a) ***General.*** Providers and suppliers furnishing items and services included in the episode bill for such items and services in accordance with existing Medicare rules.

(b) ***Reconciliation process.*** Six months after the end of each performance year, CMS does the following:

(1) Performs a reconciliation calculation to establish a reconciliation payment or repayment amount for each TEAM participant.

(2) For TEAM participants that experience a reorganization event in which one or more hospitals reorganize under the CCN of a TEAM participant, performs—

(i) Separate reconciliation calculations for each predecessor TEAM participant for episodes where the anchor hospitalization admission or the anchor procedure occurred before the effective date of the reorganization event; and

(ii) Reconciliation calculations for each new or surviving TEAM participant for episodes where the anchor hospitalization admission or anchor procedure occurred on or after the effective date of the reorganization event.

(c) ***Calculation of the reconciliation amount.*** CMS compares the reconciliation target prices described in § 512.545 and the TEAM participant's performance year spending to establish a reconciliation amount for the TEAM participant for each performance year as follows:

(1) CMS determines the performance year spending for each episode included in the performance year (other than episodes that have been canceled in accordance with § 512.537(b)) for each MS-DRG/HCPCS episode type using claims data that is available 6 months after the end of the performance year.

(2) CMS calculates and applies the high-cost outlier cap for performance year episode spending by applying the calculation described in § 512.540(b)(4) to performance year episode spending for each MS-DRG/HCPCS episode type.

(3) CMS applies the adjustments specified in § 512.545 to the preliminary target prices computed in accordance with § 512.540 to calculate the reconciliation target prices for each MS-DRG/HCPCS episode type.

(4) CMS aggregates the reconciliation target prices computed in accordance with paragraph (c)(3) of this section for all episodes included in the performance year (other than episodes that have been canceled in accordance with § 512.537(b)) for each MS-DRG/HCPCS episode type.

(5) CMS subtracts the performance year spending amount determined under paragraphs (c)(1) and (2) of this section from the reconciliation target price amount determined under paragraph (c)(4) of this section for each MS-DRG/HCPCS episode type.

(6) CMS sums the values calculated under paragraph (c)(5) of this section across all MS-DRG/HCPCS episode types to determine the reconciliation amount.

(7) Exception for low volume hospitals: CMS caps the performance year spending amount for each MS-DRG/HCPCS episode type determined under paragraphs (c)(1) and (2) of this section to equal the reconciliation target price computed in accordance with paragraph (c)(3) of this section for episode categories where the TEAM participant did not meet the low volume threshold of at least 31

episodes during the 3-year baseline period. Low volume hospital episodes, including episode categories where CMS caps performance year spending, are included in the CQS, as calculated in § 512.547(b), and stop-loss/stop-gain thresholds, as applied at paragraph (e) of this section.

(d) ***Calculation of the quality-adjusted reconciliation amount.*** CMS adjusts the reconciliation amount based on the Composite Quality Score as follows:

(1) CMS calculates a CQS adjustment percentage based on a TEAM participant's CQS, computed in accordance with § 512.547(b).

(i) CMS applies a CQS adjustment percentage up to 10 percent for positive reconciliation amounts for TEAM participants in Track 1.

(ii) CMS applies a CQS adjustment percentage up to 10 percent for positive reconciliation amounts and up to 15 percent for negative reconciliation amounts for TEAM participants in Track 2.

(iii) CMS applies a CQS adjustment percentage up to 10 percent for positive reconciliation amounts and up to 10 percent for negative reconciliation amounts for TEAM participants in Track 3.

(2) CMS multiplies the CQS adjustment percentage, computed under paragraph (d)(1) of this section, by the TEAM participant's positive or negative reconciliation amount calculated in paragraph (c) of this section to construct the CQS adjustment amount.

(3) CMS subtracts the CQS adjustment amount, computed from paragraph (d)(2) of this section, from the positive or negative reconciliation amount calculated in paragraph (c) of this section to construct the quality-adjusted reconciliation amount.

(e) ***Calculation of the net payment reconciliation amount (NPRA).*** CMS applies stop-loss and stop gain limits to the quality-adjusted reconciliation amount computed in paragraph (d) of this section to calculate the NPRA as follows:

(1) ***Limitation on loss.*** For TEAM participants in Track 3, except as provided in paragraph (e)(3) of this section, the repayment amount for a performance year cannot exceed 20 percent of the aggregated reconciliation target price amount calculated in paragraph (c)(3) of this section for the performance year. The post-episode spending calculation amount in paragraph (f) of this section is not subject to the limitation on loss.

(2) ***Limitation on gain.***

(i) For TEAM participants in Track 1, the reconciliation payment amount for a performance year cannot exceed 10 percent of the aggregated reconciliation target price amount calculated in accordance with paragraph (c)(3) of this section for the performance year.

(ii) For TEAM participants in Tracks 2, the reconciliation payment amount for a performance year cannot exceed 5 percent of the aggregated reconciliation target price amount calculated in accordance with paragraph (c)(3) of this section for the performance year.

(iii) For TEAM participants in Track 3, the reconciliation payment amount for a performance year cannot exceed 20 percent of the aggregated reconciliation target price amount calculated in accordance with paragraph (c)(3) of this section for the performance year.

(iv) The post-episode spending amount calculated in accordance with paragraph (f) of this section is not subject to the limitation on gain.

(3) ***Limitation on loss for certain providers.*** For performance years 2-5, the repayment amount for a TEAM participant in Track 2 defined at § 512.505, must not exceed 5 percent of the aggregated reconciliation target price amount calculated in accordance with paragraph (c)(3) of this section.

(f) ***Post-episode spending calculation.*** CMS calculates the post-episode spending amount as follows: If the average post-episode spending amount for a TEAM participant in the performance year being reconciled is greater than 3 standard deviations above the regional average post-episode spending amount for the performance year, then the post-episode spending amount that exceeds 3 standard deviations above the regional average post-episode spending amount for the performance year is subtracted from the NPRA for that performance year.

(g) ***Calculation of the reconciliation payment or repayment amount.***

(1) CMS applies the results of the post-episode spending calculation set forth in paragraph (f) of this section to the NPRA as follows:

(i) For TEAM participants whose post-episode spending amount does not exceed the limit calculated in paragraph (f) of this section, the reconciliation payment or repayment amount is equal to the NPRA.

(ii) If the TEAM participant's post-episode spending exceeds the limit calculated in paragraph (f) of this section, CMS subtracts the amount of post-episode spending exceeding the limit from the NPRA to calculate the reconciliation payment or repayment amount.

(2) If the amount calculated in paragraph (g)(1) of this section is positive, the TEAM participant is owed a reconciliation payment in that amount, to be paid by CMS in one lump sum payment.

(3) If the amount calculated in paragraph (g)(1) of this section is negative, CMS determines the repayment amount as follows:

(i) For TEAM participants in Track 1, the TEAM participant does not owe a repayment amount.

(ii) For TEAM participants in Track 2 or Track 3 for Performance Years 1-5, as applicable, the Team participant owes that amount as a repayment to CMS.

(h) ***TEAM reconciliation report.*** CMS issues each TEAM participant a TEAM reconciliation report for the performance year. Each TEAM reconciliation report contains the following:

(1) The total performance year spending for the TEAM participant.

(2) The TEAM participant's reconciliation target prices.

(3) The TEAM participant's reconciliation amount.

(4) The TEAM participant's composite quality score calculated in accordance with § 512.547(b).

(5) The TEAM participant's quality-adjusted reconciliation amount.

(6) The stop-loss and stop-gain limits that apply to the TEAM participant.

(7) The TEAM participant's NPRA.

(8) The TEAM participant's post-episode spending amount, if applicable.

(9) The amount of any reconciliation payment owed to the TEAM participant or repayment owed by the TEAM participant to CMS for the performance year, if applicable.

[89 FR 69914, Aug. 28, 2024, as amended at 90 FR 37207, Aug. 4, 2025]

§ 512.552 Treatment of incentive programs or add-on payments under existing Medicare payment systems.

The TEAM does not replace any existing Medicare incentive programs or add-on payments. The TEAM payments are independent of, and do not affect, any incentive programs or add-on payments under existing Medicare payment systems.

§ 512.555 Proration of payments for services that extend beyond an episode.

(a) ***General.*** CMS prorates services included in the episode that extend beyond the episode so that only those portions of the services that were furnished during the episode are included in the calculation of the actual episode payments.

(b) ***Proration of services.*** CMS prorates payments for services that extend beyond the episode for the purposes of calculating both baseline episode spending and performance year spending using the following methodology:

(1) ***Non-IPPS inpatient services.*** Non-IPPS inpatient services that extend beyond the end of the episode are prorated according to the percentage of the actual length of stay (in days) that falls within the episode.

(2) ***Home health agency services.*** Home health agency services paid under the Medicare prospective payment system in accordance with part 484, subpart E of this chapter that extend beyond the episode are prorated according to the percentage of days, starting with the first billable service date and through and including the last billable service date, that occur during the episode.

(3) ***IPPS services.*** IPPS services that extend beyond the end of the episode are prorated according to the MS-DRG geometric mean length of stay, using the following methodology:

(i) The first day of the IPPS stay is counted as 2 days.

(ii) If the actual length of stay that occurred during the episode is equal to or greater than the MS-DRG geometric mean, the full MS-DRG payment is allocated to the episode.

(iii) If the actual length of stay that occurred during the episode is less than the MS-DRG geometric mean length of stay, the MS-DRG payment amount is allocated to the episode based on the number of inpatient days that fall within the episode.

(4) If the full amount of the payment is not allocated to the episode, any remainder amount is allocated to the post-episode spending calculation (defined in § 512.550(f)).

§ 512.560 Appeals process.

(a) ***Notice of calculation error (first level of appeal).*** Subject to the limitations on review in § 512.594, if a TEAM participant wishes to dispute calculations involving a matter related to payment, reconciliation amounts, repayment amounts, the use of quality measure results in determining the composite quality score, or the application of the composite quality score during reconciliation, the TEAM participant is required to provide written notice of the calculation error, in a form and manner and by a date specified by CMS.

(1) Unless the TEAM participant provides such written notice, CMS deems the TEAM reconciliation report to be final 30 calendar days after it is issued and proceeds with the payment or repayment processes as applicable.

(2) If CMS receives a notice of a calculation error within 30 calendar days of the issuance of the TEAM reconciliation report, CMS responds in writing within 30 calendar days to either confirm that there was an error in the calculation or verify that the calculation is correct. CMS reserves the right to extend the time for its response upon written notice to the TEAM participant.

(3) Only TEAM participants may use the calculation error process described in this part.

(b) ***Exception to the appeals process.*** If the TEAM participant contests a matter that does not involve an issue contained in, or a calculation that contributes to, a TEAM reconciliation report, a notice of calculation error is not required. In these instances, if CMS does not receive a request for reconsideration from the TEAM participant within 10 calendar days of the notice of the initial reconciliation, the initial determination is deemed final and CMS proceeds with the action indicated in the initial determination. This does not apply to the limitations on review in § 512.594.

§ 512.561 Reconsideration review processes.

(a) ***Applicability of this section.*** This section is applicable only where section 1869 of the Act has been waived or is not applicable for TEAM participants. This section is only applicable to TEAM participants.

(b) ***Right to reconsideration.*** The TEAM participant may request reconsideration of a determination made by CMS only if such reconsideration is not precluded by section 1115A(d)(2) of the Act or this subpart.

(1) A request for reconsideration by the TEAM participant must satisfy the following criteria:

(i) The request must be submitted to a designee of CMS ("Reconsideration Official") who—

(A) Is authorized to receive such requests; and

(B) Did not participate in the determination that is the subject of the reconsideration request or, if applicable, the notice of calculation error process.

(ii) The request must include a copy of the initial determination issued by CMS and contain a detailed, written explanation of the basis for the dispute, including supporting documentation.

(iii) The request must be made within 30 days of the date of the initial determination for which reconsideration is being requested via email to an address as specified by CMS.

(2) Requests that do not meet the requirements of paragraph (b)(1) of this section are denied.

(3) Within 10 business days of receiving a request for reconsideration, the Reconsideration Official sends the parties a written acknowledgement of receipt of the reconsideration request. This acknowledgement sets forth the following:

(i) The review procedures.

(ii) A schedule that permits each party to submit position papers and supporting documentation in support of the party's position for consideration by the reconsideration official.

(4) The TEAM participant must satisfy the notice of calculation error requirements specified in this part before submitting a reconsideration request under paragraph (b) of this section.

(c) ***Standards for reconsideration.***

(1) The parties must continue to fulfill all responsibilities and obligations under TEAM during the course of any dispute arising under this part.

(2) The reconsideration consists of a review of documentation that is submitted timely and in accordance with the standards specified by the reconsideration official.

(3) The burden of proof is on the TEAM participant to demonstrate to the reconsideration official with clear and convincing evidence that the determination is inconsistent with the terms of this subpart.

(d) ***Reconsideration determination.***

(1) The reconsideration determination is based solely upon—

(i) Position papers and supporting documentation that are timely submitted to the reconsideration official per the schedule defined in paragraph (b)(3)(ii) and meet the standards for submission under paragraph (b)(1) of this section; and

(ii) Documents and data that were timely submitted to CMS in the required format before CMS made the determination that is the subject of the reconsideration request.

(2) The reconsideration official issues the reconsideration determination to CMS and to the TEAM participant in writing.

(3) Absent unusual circumstances, in which case the reconsideration official reserves the right to an extension upon written notice to the TEAM participant, the reconsideration determination is issued within 60 days of receipt of timely filed position papers and supporting documentation per the schedule defined in paragraph (b)(3)(ii) of this section.

(4) The reconsideration determination is final and binding 30 days after its issuance, unless the TEAM participant or CMS timely requests review of the reconsideration determination in accordance with paragraphs (e)(1) and (2) of this section.

(e) ***CMS Administrator review.*** The TEAM participant or CMS may request that the CMS Administrator review the reconsideration determination.

(1) The request must be made via email within 30 days of the date of the reconsideration determination to the address specified by CMS.

(2) The request must include a copy of the reconsideration determination and a detailed written explanation of why the TEAM participant or CMS disagrees with the reconsideration determination.

(3) The CMS Administrator promptly sends the parties a written acknowledgement of receipt of the request for review.

(4) The CMS Administrator sends the parties notice of the following:

(i) Whether the request for review is granted or denied.

(ii) If the request for review is granted, the review procedures and a schedule that permits each party to submit a brief in support of the party's position for consideration by the CMS Administrator.

(5) If the request for review is denied, the reconsideration determination is final and binding as of the date the request for review is denied.

(6) If the request for review is granted—

(i) The record for review consists solely of—

(A) Timely submitted briefs and the evidence contained in the record of the proceedings before the reconsideration official; and

(B) Evidence as set forth in the documents and data described in paragraph (d)(1)(ii) of this section;

(ii) The CMS Administrator reviews the record and issues to CMS and to the TEAM participant a written determination; and

(iii) The written determination of the CMS Administrator is final and binding as of the date the written determination is sent.

DATA SHARING AND OTHER REQUIREMENTS

§ 512.562 Data sharing with TEAM participants.

(a) ***General.*** CMS shares certain beneficiary-identifiable data as described in paragraphs (b), (c), and (e) of this section and certain regional aggregate data as described in paragraph (d) of this section with TEAM participants regarding TEAM beneficiaries and performance under the model.

(b) ***Beneficiary-identifiable claims data.*** CMS shares beneficiary-identifiable claims data with TEAM participants as follows:

(1) CMS makes available certain beneficiary-identifiable claims data described in paragraph (b)(5) of this section for TEAM participants to request for purposes of conducting health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 regarding their TEAM beneficiaries.

(2) A TEAM participant that wishes to receive beneficiary-identifiable claims data for its TEAM beneficiaries must do all of the following:

(i) Submit a formal request for the data on at least an annual basis in a manner and form and by a date specified by CMS, indicating their selection of summary beneficiary-identifiable data, raw beneficiary-identifiable data, or both, and attest that—

(A) The TEAM participant is requesting claims data of TEAM beneficiaries who would be in an episode during the baseline period or performance year, as a HIPAA covered entity.

(B) The TEAM participant's request reflects the minimum data necessary, as set forth in paragraph (c) of this section, for the TEAM participant 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.

(C) The TEAM participant's use of claims data is limited to developing processes and engaging in appropriate activities related to coordinating care, improving the quality and efficiency of care, and conducting population-based activities relating to improving health or reducing health care costs that are applied uniformly to all TEAM beneficiaries, in an episode during the baseline period or performance year, and that these data are not to be used to reduce, limit or restrict care for specific Medicare beneficiaries.

(ii) Sign and submit a TEAM data sharing agreement, as defined in § 512.505, with CMS as set forth in paragraph (e) of this section.

(3) CMS shares this beneficiary-identifiable claims data with a TEAM participant in accordance with applicable privacy and security laws and established privacy and security protections.

(4) CMS omits from the beneficiary-identifiable claims data any information that is subject to the regulations in 42 CFR part 2 governing the confidentiality of substance use disorder patient records.

(5) The beneficiary-identifiable claims data includes, when available, the following:

(i) Unrefined (raw) Medicare Parts A and B beneficiary-identifiable claims data for TEAM beneficiaries in an episode during the 3-year baseline period and performance year.

(ii) Summarized (summary) Medicare Parts A and B beneficiary-identifiable claims data for TEAM beneficiaries in an episode during the 3-year baseline period and performance year.

(6) CMS makes available the beneficiary-identifiable claims data for retrieval by TEAM participants at the following frequency:

(i) Annually, at least 1 month prior to every performance year for baseline period data, based on the baseline periods described in § 512.540(b)(2).

(ii) Monthly during the performance year and for up to 6 months after the performance year for performance year data.

(c) ***Minimum necessary data.*** The TEAM participant must limit its request for beneficiary-identifiable data under paragraph (b) of this section to the minimum necessary Parts A and B data elements which may include, but are not limited to the following:

(1) Medicare beneficiary identifier (ID).

(2) Procedure code.

(3) Sex.

(4) Diagnosis code.

(5) Claim ID.

(6) The from and through dates of service.

(7) The provider or supplier ID.

(8) The claim payment type.

(9) Date of birth and death, if applicable.

(10) Tax identification number.

(11) National provider identifier.

(d) ***Regional aggregate data.***

(1) CMS shares regional aggregate data for the 3-year baseline period and performance years with TEAM participants as follows:

(i) Shares 3-year baseline period regional aggregate data annually at least 1 month before the performance year, based on the baseline periods described in § 512.540(b)(2).

(ii) Shares performance year regional aggregate data on a monthly basis during the performance year and for up to 6 months after the performance year.

(2) Regional aggregate data—

(i) Is aggregated based on all Parts A and B claims associated with episodes in TEAM for the U.S. Census Division in which the TEAM participant is located;

(ii) Summarizes average episode spending for episodes in TEAM in the U.S. Census Division in which the TEAM participant is located; and

(iii) Is de-identified in accordance with 45 CFR 164.514(b).

(e) ***TEAM data sharing agreement.***

(1) A TEAM participant who wishes to retrieve the beneficiary-identifiable data specified in paragraph (b) of this section, must complete and submit, on at least an annual basis, a signed TEAM data sharing agreement, as defined in § 512.505, to be provided in a form and manner and by a date specified by CMS, under which the TEAM participant agrees:

(i) To comply with the requirements for use and disclosure of this beneficiary-identifiable data that are imposed on covered entities by the HIPAA regulations and the requirements of the TEAM set forth in this part.

(ii) To comply with additional privacy, security, breach notification, and data retention requirements specified by CMS.

(iii) To contractually bind each downstream recipient of the beneficiary-identifiable data that is a business associate of the TEAM participant to the same terms and conditions to which the TEAM participant is itself bound in its TEAM data sharing agreement with CMS as a condition of the business associate's receipt of the beneficiary-identifiable data retrieved by the TEAM participant under TEAM.

(iv) That if the TEAM participant misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the TEAM data sharing agreement, CMS may deem the TEAM participant ineligible to retrieve beneficiary-identifiable data under paragraph (b) of this section for any amount of time, and the TEAM participant may be subject to additional sanctions and penalties available under the law.

(2) A TEAM participant must comply with all applicable laws and the terms of the TEAM data sharing agreement in order to retrieve the beneficiary-identifiable data.

[89 FR 69914, Aug. 28, 2024, as amended at 90 FR 37208, Aug. 4, 2025]

§ 512.563 Health data reporting.

(a)-(b) [Reserved]

(c) ***Demographic data collection and reporting.*** For all performance years, the TEAM participant may voluntarily collect and submit to CMS, in a form and manner and by the dates specified by CMS, demographic data of TEAM beneficiaries that are willing to share demographic data elements with the TEAM participant and CMS.

[89 FR 69914, Aug. 28, 2024, as amended at 90 FR 37208, Aug. 4, 2025]

§ 512.564 Referral to primary care services.

(a) A TEAM participant must include in hospital discharge planning a referral to an established supplier of primary care services, as recorded on admission to the hospital or hospital outpatient department, for a TEAM beneficiary, on or prior to discharge from an anchor hospitalization or anchor procedure. In the event an established supplier of primary care services is not recorded on admission to the hospital or hospital outpatient department, the TEAM participant must include in hospital discharge planning a referral to a supplier of primary care services for a TEAM beneficiary, on or prior to discharge from an anchor hospitalization or anchor procedure.

(b) In making the referral described in paragraph (a) of this section, the TEAM participant must comply with beneficiary freedom of choice, as described in § 512.582(a).

(c) A TEAM participant that does not comply with paragraph (a) of this section, may be subject to remedial action as described in § 512.592.

[89 FR 69914, Aug. 28, 2024, as amended at 90 FR 37208, Aug. 4, 2025]

Financial Arrangements and Beneficiary Incentives

§ 512.565 Sharing arrangements.

(a) ***General.***

(1) A TEAM participant may enter into a sharing arrangement with a TEAM collaborator to make a gainsharing payment, or to receive an alignment payment, or both. A TEAM participant must not make a gainsharing payment to a TEAM collaborator or receive an alignment payment from a TEAM collaborator except in accordance with a sharing arrangement.

(2) A sharing arrangement must comply with the provisions of this section and all other applicable laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements.

(3) TEAM participants must develop, maintain, and use a set of written policies for selecting individuals and entities to be TEAM collaborators.

(i) These policies must contain criteria related to, and inclusive of, the quality of care delivered by the potential TEAM collaborator and the provision of TEAM activities.

(ii) The selection criteria cannot be based directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the TEAM participant, any TEAM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a TEAM participant, TEAM collaborator, collaboration agent, or downstream collaboration agent.

(iii) A selection criterion that considers whether a potential TEAM collaborator has performed a reasonable minimum number of services that would qualify as TEAM activities, as determined by the TEAM participant, will be deemed not to violate the volume or value standard if the purpose of the criterion is to ensure the quality of care furnished to TEAM beneficiaries.

(4) If a TEAM participant enters into a sharing arrangement, its compliance program must include oversight of sharing arrangements and compliance with the applicable requirements of TEAM.

(b) ***Requirements.***

(1) A sharing arrangement must be in writing and signed by the parties, and entered into before care is furnished to TEAM beneficiaries under the sharing arrangement.

(2) Participation in a sharing arrangement must be voluntary and without penalty for nonparticipation.

(3) The sharing arrangement must require the TEAM collaborator and its employees, contractors (including collaboration agents), and subcontractors (including downstream collaboration agents) to comply with all of the following:

(i) The applicable provisions of this part (including requirements regarding beneficiary notifications, access to records, record retention, and participation in any evaluation, monitoring, compliance, and enforcement activities performed by CMS or its designees).

(ii) All applicable Medicare provider enrollment requirements at § 424.500 of this chapter, including having a valid and active TIN or NPI, during the term of the sharing arrangement.

(iii) All other applicable laws and regulations.

(4) The sharing arrangement must require the TEAM collaborator to have or be covered by a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of TEAM that apply to its role as a TEAM collaborator, including any distribution arrangements.

(5) The sharing arrangement must not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care.

(6) The board or other governing body of the TEAM participant must have responsibility for overseeing the TEAM participant's participation in TEAM, its arrangements with TEAM collaborators, its payment of gainsharing payments, its receipt of alignment payments, and its use of beneficiary incentives in TEAM.

(7) The specifics of the agreement must be documented in writing and must be made available to CMS upon request (as outlined in § 512.590).

(8) The sharing arrangement must specify the following:

(i) The purpose and scope of the sharing arrangement.

(ii) The obligations of the parties, including specified TEAM activities and other services to be performed by the parties under the sharing arrangement.

(iii) The date range for which the sharing arrangement is effective.

(iv) The financial or economic terms for payment, including the following:

(A) Eligibility criteria for a gainsharing payment.

(B) Eligibility criteria for an alignment payment.

(C) Frequency of gainsharing or alignment payments.

(D) Methodology and accounting formula for determining the amount of a gainsharing payment or alignment payment.

(9) The sharing arrangement must not—

(i) Induce the TEAM participant, TEAM collaborator, or any employees, contractors, or subcontractors of the TEAM participant or TEAM collaborator to reduce or limit medically necessary services to any Medicare beneficiary; or

(ii) Restrict the ability of a TEAM collaborator to make decisions in the best interests of its patients, including the selection of devices, supplies, and treatments.

(c) ***Gainsharing payment, alignment payment, and internal cost savings conditions and restrictions.***

(1) Gainsharing payments, if any, must—

(i) Be derived solely from reconciliation payment amounts, or internal cost savings, or both;

(ii) Be distributed on an annual basis (not more than once per calendar year);

(iii) Not be a loan, advance payment, or payment for referrals or other business; and

(iv) Be clearly identified as a gainsharing payment at the time it is paid.

(2)

(i) To be eligible to receive a gainsharing payment, a TEAM collaborator must meet quality of care criteria for the performance year for which the TEAM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment. The quality-of-care criteria must be established by the TEAM participant and directly relate to the episode.

(ii) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a TEAM collaborator other than ACO, PGP, NPPGP, or TGP must have directly furnished a billable item or service to a TEAM beneficiary during an episode that was attributed to the same performance year for which the TEAM participant accrued the internal cost savings or earned the reconciliation payment amount or repayment amount that comprises the gainsharing payment or the alignment payment.

(iii) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a TEAM collaborator that is a PGP, NPPGP, or TGP must meet the following criteria:

(A) The PGP, NPPGP, or TGP must have billed for an item or service that was rendered by one or more PGP member, NPPGP member, or TGP member respectively to a TEAM beneficiary during an episode that was attributed to the same performance year for which the TEAM participant accrued the internal cost savings or earned the reconciliation payment amount or repayment amount that comprises the gainsharing payment or the alignment payment.

(B) The PGP, NPPGP, or TGP must have contributed to TEAM activities and been clinically involved in the care of TEAM beneficiaries during the same performance year for which the TEAM participant accrued the internal cost savings or earned the reconciliation payment amount or repayment amount that comprises the gainsharing payment or the alignment payment. A non-exhaustive list of examples where, a PGP, NPPGP, or TGP might have been clinically involved in the care of TEAM beneficiaries includes—

(*1*) Providing care coordination services to TEAM beneficiaries during or after inpatient admission;

(*2*) Engaging with a TEAM participant in care redesign strategies, and performing a role in implementing such strategies, that are designed to improve the quality of care for episodes and reduce episode spending; or

(*3*) In coordination with other providers and suppliers (such as PGP members, NPPGP members, or TGP members; the TEAM participant; and post-acute care providers), implementing strategies designed to address and manage the comorbidities of TEAM beneficiaries.

(iv) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a TEAM collaborator that is an ACO must meet the following criteria:

(A) The ACO must have had an ACO provider/supplier that directly furnished, or an ACO participant that billed for, an item or service that was rendered to a TEAM beneficiary during an episode that was attributed to the same performance year for which the TEAM participant accrued the internal cost savings or earned the reconciliation payment amount or repayment amount that comprises the gainsharing payment or the alignment payment; and

(B) The ACO must have contributed to TEAM activities and been clinically involved in the care of TEAM beneficiaries during the performance year for which the TEAM participant accrued the internal cost savings or earned the reconciliation payment amount or repayment amount that comprises the gainsharing payment or the alignment payment. A non-exhaustive list of ways in which an ACO might have been clinically involved in the care of TEAM beneficiaries could include—

(*1*) Providing care coordination services to TEAM beneficiaries during and/or after inpatient admission;

(*2*) Engaging with a TEAM participant in care redesign strategies and performing a role in implementing such strategies that are designed to improve the quality of care and reduce spending for episodes; or

(*3*) In coordination with providers and suppliers (such as ACO participants, ACO providers/suppliers, the TEAM participant, and post-acute care providers), implementing strategies designed to address and manage the comorbidities of TEAM beneficiaries.

(3) The methodology for accruing, calculating and verifying internal cost savings will be determined by the TEAM participant. The methodology—

(i) Must be transparent, measurable, and verifiable in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book).

(ii) Used to calculate internal cost savings must reflect the actual, internal cost savings achieved by the TEAM participant through the documented implementation of TEAM activities identified by the TEAM participant and must exclude—

(A) Any savings realized by any individual or entity that is not the TEAM participant; and

(B) “Paper” savings from accounting conventions or past investment in fixed costs.

(4) The amount of any gainsharing payments must be determined in accordance with a methodology that is based solely on quality of care and the provision of TEAM activities. The methodology may take into account the amount of TEAM activities provided by a TEAM collaborator relative to other TEAM collaborators.

(5) For a performance year, the aggregate amount of all gainsharing payments that are derived from reconciliation payment amounts must not exceed the amount of that year's reconciliation payment amount.

(6) No entity or individual, whether a party to a sharing arrangement or not, may condition the opportunity to make or receive gainsharing payments or to make or receive alignment payments directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the TEAM participant, any TEAM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a TEAM participant, TEAM collaborator, collaboration agent, or downstream collaboration agent.

(7) A TEAM participant must not make a gainsharing payment to a TEAM collaborator if CMS has notified the TEAM participant that such TEAM collaborator is subject to any action by CMS, HHS or any other governmental entity, or its designees, for noncompliance with this part or the fraud and abuse laws, for the provision of substandard care to TEAM beneficiaries or other integrity problems, or for any other program integrity problems or noncompliance with any other laws or regulations.

(8) The sharing arrangement must require the TEAM participant to recoup any gainsharing payment that contained funds derived from a CMS overpayment on a reconciliation payment amount or was based on the submission of false or fraudulent data.

(9) Alignment payments from a TEAM collaborator to a TEAM participant may be made at any interval that is agreed upon by both parties, and must not be—

(i) Issued, distributed, or paid prior to the calculation by CMS of a repayment amount; payment;

(ii) Loans, advance payments, or payments for referrals or other business; or

(iii) Assessed by a TEAM participant in the absence of a repayment amount.

(10) The TEAM participant must not receive any amounts under a sharing arrangement from a TEAM collaborator that are not alignment payments.

(11) For a performance year, the aggregate amount of all alignment payments received by the TEAM participant must not exceed 50 percent of the TEAM participant's repayment amount.

(12) The aggregate amount of all alignment payments from a TEAM collaborator to the TEAM participant may not be greater than—

(i) With respect to a TEAM collaborator other than an ACO, 25 percent of the TEAM participant's repayment amount.

(ii) With respect to a TEAM collaborator that is an ACO, 50 percent of the TEAM participant's repayment amount.

(13) The amount of any alignment payments must be determined in accordance with a methodology that does not directly account for the volume or value of past or anticipated referrals or business otherwise generated by, between or among the TEAM participant, any TEAM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a TEAM participant, TEAM collaborator, collaboration agent, or downstream collaboration agent.

(14) All gainsharing payments and any alignment payments must be administered by the TEAM participant in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book).

(15) All gainsharing payments and alignment payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(d) ***Documentation requirements.***

(1) TEAM participants must—

(i) Document the sharing arrangement contemporaneously with the establishment of the arrangement;

(ii) Publicly post (and update on at least a quarterly basis) on a web page on the TEAM participant's website—

(A) Accurate lists of all current TEAM collaborators, including the TEAM collaborators' names and addresses as well as accurate historical lists of all TEAM collaborators.

(B) Written policies for selecting individuals and entities to be TEAM collaborators as required by § 512.565(a)(3).

(iii) Maintain, and require each TEAM collaborator to maintain, contemporaneous documentation with respect to the payment or receipt of any gainsharing payment or alignment payment that includes, at a minimum—

(A) Nature of the payment (gainsharing payment or alignment payment);

(B) Identity of the parties making and receiving the payment;

(C) Date of the payment;

(D) Amount of the payment; and

(E) Date and amount of any recoupment of all or a portion of a TEAM collaborator's gainsharing payment.

(F) Explanation for each recoupment, such as whether the TEAM collaborator received a gainsharing payment that contained funds derived from a CMS overpayment of a reconciliation payment or was based on the submission of false or fraudulent data.

(2) The TEAM participant must keep records of all of the following:

(i) Its process for determining and verifying its potential and current TEAM collaborators' eligibility to participate in Medicare.

(ii) Its plan to track internal cost savings.

(iii) Information on the accounting systems used to track internal cost savings.

(iv) A description of current health information technology, including systems to track reconciliation payment amounts, repayment amounts, and internal cost savings.

(v) Its plan to track gainsharing payments and alignment payments.

(3) The TEAM participant must retain and provide access to and must require each TEAM collaborator to retain and provide access to, the required documentation in accordance with § 512.586.

§ 512.568 Distribution arrangements.

(a) ***General.***

(1) An ACO, PGP, NPPGP, or TGP that is a TEAM collaborator and has entered into a sharing arrangement with a TEAM participant may distribute all or a portion of any gainsharing payment it receives from the TEAM participant only in accordance with a distribution arrangement.

(2) All distribution arrangements must comply with the provisions of this section and all other applicable laws and regulations, including the fraud and abuse laws.

(b) ***Requirements.***

(1) All distribution arrangements must be in writing and signed by the parties, contain the effective date of the agreement, and be entered into before care is furnished to TEAM beneficiaries under the distribution arrangement.

(2) Participation in a distribution arrangement must be voluntary and without penalty for nonparticipation.

(3) The distribution arrangement must require the collaboration agent to comply with all applicable laws and regulations.

(4) The opportunity to make or receive a distribution payment must not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the TEAM participant, any TEAM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a TEAM participant, TEAM collaborator, collaboration agent, or downstream collaboration agent.

(5) The amount of any distribution payments from an ACO, from an NPPGP to an NPPGP member, or from a TGP to a TGP member, must be determined in accordance with a methodology that is solely based on quality of care and the provision of TEAM activities and that may take into account the amount of such TEAM activities provided by a collaboration agent relative to other collaboration agents.

(6) The amount of any distribution payments from a PGP must be determined in accordance with a methodology that is solely based on quality of care and the provision of TEAM activities and that may take into account the amount of such TEAM activities provided by a collaboration agent relative to other collaboration agents.

(7) A collaboration agent is eligible to receive a distribution payment only if the collaboration agent furnished or billed for an item or service rendered to a TEAM beneficiary during an episode that was attributed to the same performance year for which the TEAM participant accrued the internal cost savings or earned the reconciliation payment amount that comprises the gainsharing payment being distributed.

(8) With respect to the distribution of any gainsharing payment received by an ACO, PGP, NPPGP, or TGP, the total amount of all distribution payments for a performance year must not exceed the amount of the gainsharing payment received by the TEAM collaborator from the TEAM participant for the same performance year.

(9) All distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(10) The collaboration agent must retain the ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

(11) The distribution arrangement must not—

(i) Induce the collaboration agent to reduce or limit medically necessary items and services to any Medicare beneficiary; or

(ii) Reward the provision of items and services that are medically unnecessary.

(12) The TEAM collaborator must maintain contemporaneous documentation regarding distribution arrangements in accordance with § 512.586, including all of the following:

(i) The relevant written agreements.

(ii) The date and amount of any distribution payment(s).

(iii) The identity of each collaboration agent that received a distribution payment.

(iv) A description of the methodology and accounting formula for determining the amount of any distribution payment.

(13) The TEAM collaborator may not enter into a distribution arrangement with any individual or entity that has a sharing arrangement with the same TEAM participant.

(14) The TEAM collaborator must retain and provide access to and must require collaboration agents to retain and provide access to, the required documentation in accordance with § 512.586.

§ 512.570 Downstream distribution arrangements.

(a) ***General.***

(1) An ACO participant that is a PGP, NPPGP, or TGP and that has entered into a distribution arrangement with a TEAM collaborator that is an ACO, may distribute all or a portion of any distribution payment it receives from the TEAM collaborator only in accordance with a downstream distribution arrangement.

(2) All downstream distribution arrangements must comply with the provisions of this section and all applicable laws and regulations, including the fraud and abuse laws.

(b) ***Requirements.***

(1) All downstream distribution arrangements must be in writing and signed by the parties, contain the effective date of the agreement, and be entered into before care is furnished to TEAM beneficiaries under the downstream distribution arrangement.

(2) Participation in a downstream distribution arrangement must be voluntary and without penalty for nonparticipation.

(3) The downstream distribution arrangement must require the downstream collaboration agent to comply with all applicable laws and regulations.

(4) The opportunity to make or receive a downstream distribution payment must not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the TEAM participant, any TEAM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a TEAM participant, TEAM collaborator, collaboration agent, or downstream collaboration agent.

(5) The amount of any downstream distribution payments from an NPPGP to an NPPGP member or from a TGP to a TGP member must be determined in accordance with a methodology that is solely based on quality of care and the provision of TEAM activities and that may take into account the amount of such TEAM activities provided by a downstream collaboration agent relative to other downstream collaboration agents.

(6) The amount of any downstream distribution payments from a PGP must be determined in accordance with a methodology that is solely based on quality of care and the provision of TEAM activities and that may take into account the amount of such TEAM activities provided by a downstream collaboration agent relative to other downstream collaboration agents.

(7) A downstream collaboration agent is eligible to receive a downstream distribution payment only if the downstream collaboration agent furnished an item or service to a TEAM beneficiary during an episode that is attributed to the same performance year for which the TEAM participant accrued the internal cost savings or earned the reconciliation payment amount that comprises the gainsharing payment from which the ACO made the distribution payment to the PGP, NPPGP, or TGP that is an ACO participant.

(8) The total amount of all downstream distribution payments made to downstream collaboration agents must not exceed the amount of the distribution payment received by the PGP, NPPGP, or TGP from the ACO.

(9) All downstream distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(10) The downstream collaboration agent must retain his or her ability to make decisions in the best interests of the beneficiary, including the selection of devices, supplies, and treatments.

(11) The downstream distribution arrangement must not—

(i) Induce the downstream collaboration agent to reduce or limit medically necessary services to any Medicare beneficiary; or

(ii) Reward the provision of items and services that are medically unnecessary.

(12) The PGP, NPPGP, or TGP must maintain contemporaneous documentation regarding downstream distribution arrangements in accordance with § 512.586, including the following:

(i) The relevant written agreements.

(ii) The date and amount of any downstream distribution payment.

(iii) The identity of each downstream collaboration agent that received a downstream distribution payment.

(iv) A description of the methodology and accounting formula for determining the amount of any downstream distribution payment.

(13) The PGP, NPPGP, or TGP may not enter into a downstream distribution arrangement with any PGP member, NPPGP member, or TGP member who has—

(i) A sharing arrangement with a TEAM participant.

(ii) A distribution arrangement with the ACO that the PGP, NPPGP, or TGP is a participant in.

(14) The PGP, NPPGP, or TGP must retain and provide access to, and must require downstream collaboration agents to retain and provide access to, the required documentation in accordance with § 512.586.

§ 512.575 TEAM beneficiary incentives.

(a) ***General.*** TEAM participants may choose to provide in-kind patient engagement incentives including but not limited to items of technology to TEAM beneficiaries in an episode, subject to the following conditions:

(1) The incentive must be provided directly by the TEAM participant or by an agent of the TEAM participant under the TEAM participant's direction and control to the TEAM beneficiary during an episode.

(2) The item or service provided must be reasonably connected to medical care provided to a TEAM beneficiary during an episode.

(3) The item or service must be a preventive care item or service or an item or service that advances a clinical goal, as listed in paragraph (c) of this section, for a TEAM beneficiary in an episode by engaging the TEAM beneficiary in better managing his or her own health.

(4) The item or service must not be tied to the receipt of items or services outside the episode.

(5) The item or service must not be tied to the receipt of items or services from a particular provider or supplier.

(6) The availability of the items or services must not be advertised or promoted, except that a TEAM beneficiary may be made aware of the availability of the items or services at the time the TEAM beneficiary could reasonably benefit from them.

(7) The cost of the items or services must not be shifted to any Federal health care program, as defined at section 1128B(f) of the Act.

(b) ***Technology provided to a TEAM beneficiary.*** TEAM beneficiary engagement incentives involving technology are subject to the following additional conditions:

(1) Items or services involving technology provided to a TEAM beneficiary may not exceed $1,000 in retail value for any one TEAM beneficiary during any one episode.

(2) Items or services involving technology provided to a TEAM beneficiary must be the minimum necessary to advance a clinical goal, as listed in paragraph (c) of this section, for a beneficiary in an episode.

(3) Items of technology exceeding $75 in retail value must—

(i) Remain the property of the TEAM participant; and

(ii) Be retrieved from the TEAM beneficiary at the end of the episode, with documentation of the ultimate date of retrieval. The TEAM participant must document all retrieval attempts. In cases when the item of technology is not able to be retrieved, the TEAM participant must determine why the item was not retrievable. If it was determined that the item was misappropriated (if it were sold, for example), the TEAM participant must take steps to prevent future beneficiary incentives for that TEAM beneficiary. Following this process, documented, diligent, good faith attempts to retrieve items of technology will be deemed to meet the retrieval requirement.

(c) ***Clinical goals of TEAM.*** The following are the clinical goals of TEAM, which may be advanced through TEAM beneficiary incentives:

(1) Beneficiary adherence to drug regimens.

(2) Beneficiary adherence to a care plan.

(3) Reduction of readmissions and complications following an episode.

(4) Management of chronic diseases and conditions that may be affected by the TEAM procedure.

(d) ***Documentation of TEAM beneficiary incentives.***

(1) TEAM participants must maintain documentation of items and services furnished as beneficiary incentives that exceed $25 in retail value.

(2) The documentation must be established contemporaneously with the provision of the items and services with a record established and maintained to include at least the following:

(i) The date the incentive is provided.

(ii) The identity of the TEAM beneficiary to whom the item or service was provided.

(3) The documentation regarding items of technology exceeding $75 in retail value must also include contemporaneous documentation of any attempt to retrieve technology at the end of an episode, or why the items were not retrievable, as described in paragraph (b)(3) of this section.

(4) The TEAM participant must retain and provide access to the required documentation in accordance with § 512.586.

§ 512.576 Application of the CMS-sponsored model arrangements and patient incentives safe harbor.

(a) ***Application of the CMS-sponsored model arrangements safe harbor.*** CMS has determined that the Federal Anti-Kickback Statute Safe Harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)(1)) is available to protect remuneration furnished in TEAM in the form of the sharing arrangement's gainsharing payments and alignment payments, the distribution arrangement's distribution payments, and the downstream distribution arrangement's distribution payments that meet all safe harbor requirements set forth in 42 CFR 1001.952(ii), and §§ 512.565, 512.568, 512.570.

(b) ***Application of the CMS-sponsored model patient incentives safe harbor.*** CMS has determined that the Federal Anti-Kickback Statute Safe Harbor for CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(2)) is available to protect TEAM beneficiary incentives that meet all safe harbor requirements set forth in 42 CFR 1001.952(ii) and § 512.575.

§ 512.580 TEAM Medicare Program Waivers.

(a) ***Waiver of certain telehealth requirements*** —

(1) ***Waiver of the geographic site requirements.*** Except for the geographic site requirements for a face-to-face encounter for home health certification, CMS waives the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act for episodes being tested in TEAM solely for services that—

(i) May be furnished via telehealth under existing Medicare program requirements; and

(ii) Are included in the episode in accordance with § 512.525(e).

(2) ***Waiver of the originating site requirements.*** Except for the originating site requirements for a face-to-face encounter for home health certification, CMS waives the originating site requirements under section 1834(m)(4)I(ii)(I) through (VIII) of the Act for episodes to permit a telehealth visit to originate in the beneficiary's home or place of residence solely for services that—

(i) May be furnished via telehealth under existing Medicare program requirements; and

(ii) Are included in the episode in accordance with § 512.525(e).

(3) ***Waiver of selected payment provisions.***

(i) CMS waives the payment requirements under section 1834(m)(2)(A) of the Act so that the facility fee normally paid by Medicare to an originating site for a telehealth service is not paid if the service is originated in the beneficiary's home or place of residence.

(ii) CMS waives the payment requirements under section 1834(m)(2)(B) of the Act to allow the distant site payment for telehealth home visit HCPCS codes unique to TEAM.

(4) ***Other requirements.*** All other requirements for Medicare coverage and payment of telehealth services continue to apply, including the list of specific services approved to be furnished by telehealth.

(b) ***Waiver of the SNF 3-day rule*** —

(1) ***Episodes initiated by an anchor hospitalization.*** CMS waives the SNF 3-day rule for coverage of a SNF stay within 30 days of the date of discharge from the anchor hospitalization for a beneficiary who is a TEAM beneficiary on the date of discharge from the anchor hospitalization if the SNF is identified on the applicable calendar quarter list of qualified SNFs at the time of the TEAM beneficiary's admission to the SNF.

(2) ***Episodes initiated by an anchor procedure.*** CMS waives the SNF 3-day rule for coverage of a SNF stay within 30 days of the date of service of the anchor procedure for a beneficiary who is a TEAM beneficiary on the date of service of the anchor procedure if the SNF is identified on the applicable calendar quarter list of qualified SNFs at the time of the TEAM beneficiary's admission to the SNF.

(3) ***Determination of qualified SNFs.*** CMS determines the qualified SNFs for each calendar quarter based on a review of the most recent rolling 12 months of overall star ratings on the Five-Star Quality Rating System for SNFs on the Nursing Home Compare website.

(i) Qualified SNFs are rated an overall of 3 stars or better for at least 7 of the 12 months.

(ii) Qualified SNFs include providers furnishing SNF services under swing bed agreements, which will not be subject to the star ratings requirement.

(4) ***Posting of qualified SNFs.*** CMS posts to the CMS website the list of qualified SNFs in advance of the calendar quarter.

(5) ***Financial liability for non-covered SNF services.*** If CMS determines that the waiver requirements specified in paragraph (b) of this section were not met, the following apply:

(i) CMS makes no payment to a SNF for SNF services if the SNF admits a TEAM beneficiary who has not had a qualifying anchor hospitalization or anchor procedure.

(ii) In the event that CMS makes no payment for SNF services furnished by a SNF as a result of paragraph (b)(5)(i) of this section, the beneficiary protections specified in paragraph (b)(5)(iii) of this section apply, unless the TEAM participant has provided the beneficiary with a discharge planning notice in accordance with § 512.582(b)(3).

(iii) If the TEAM participant does not provide the beneficiary with a discharge planning notice in accordance with § 512.582(b)(3)—

(A) The SNF must not charge the beneficiary for the expenses incurred for such services;

(B) The SNF must return to the beneficiary any monies collected for such services; and

(C) The TEAM participant is financially liable for the expenses incurred for such services.

(6) ***Coverage of SNF services and discharge planning notification.*** If the TEAM participant provided a discharge planning notice to the beneficiary in accordance with § 512.582(b)(3), then normal SNF coverage requirements apply, and the beneficiary may be financially liable for non-covered SNF services.

(c) ***Other requirements.*** All other Medicare rules for coverage and payment of Part A-covered services continue to apply except as otherwise waived in this part.

[89 FR 69914, Aug. 28, 2024, as amended at 90 FR 37208, Aug. 4, 2025]

GENERAL PROVISIONS

§ 512.582 Beneficiary protections.

(a) ***Beneficiary freedom of choice.***

(1) A TEAM participant, TEAM collaborators, collaboration agents, downstream collaboration agent and downstream participants must not restrict Medicare beneficiaries' ability to choose to receive care from any provider or supplier.

(2) The TEAM participant and its downstream participants must not commit any act or omission, nor adopt any policy that inhibits beneficiaries from exercising their freedom to choose to receive care from any provider or supplier or from any health care provider who has opted out of Medicare. The TEAM participant and its downstream participants may communicate to TEAM beneficiaries the benefits of receiving care with the TEAM participant, if otherwise consistent with the requirements of this part and applicable law.

(3) As part of discharge planning and referral, TEAM participants must provide a complete list of HHAs, SNFs, IRFs, or LTCHs that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of a SNF, IRF, or LTCH, in the geographic area requested by the patient.

(i) This list must be presented to TEAM beneficiaries for whom home health care, SNF, IRF, or LTCH services are medically necessary.

(ii) TEAM participants must specify on the list those post-acute care providers on the list with whom they have a sharing arrangement.

(iii) TEAM participants may recommend preferred providers and suppliers, consistent with applicable statutes and regulations.

(iv) TEAM participants may not limit beneficiary choice to any list of providers or suppliers in any manner other than as permitted under applicable statutes and regulations.

(v) TEAM participants must take into account patient and family preferences for choice of provider and supplier when they are expressed.

(4) TEAM participants may not charge any TEAM collaborator a fee to be included on any list of preferred providers or suppliers, nor may the TEAM participant accept such payments.

(b) ***Required beneficiary notification*** —

(1) ***TEAM participant beneficiary notification*** —

(i) ***Notification to beneficiaries.*** Each TEAM participant must provide written notification to any TEAM beneficiary that meets the criteria in § 512.535 of his or her inclusion in the TEAM model.

(ii) ***Timing of notification.*** Prior to discharge from the anchor hospitalization, or prior to discharge from the anchor procedure, as applicable, the TEAM participant must provide the TEAM beneficiary with a beneficiary notification as described in paragraph (b)(1)(iv) of this section.

(iii) ***List of beneficiaries who have received a notification.*** The TEAM participant must be able to generate a list of all beneficiaries who have received such notification, including the date on which the notification was provided to the beneficiary, to CMS or its designee upon request.

(iv) ***Content of notification.*** The beneficiary notification must contain all of the following:

(A) A detailed explanation of TEAM and how it might be expected to affect the beneficiary's care.

(B) Notification that the beneficiary retains freedom of choice to choose providers and services.

(C) Explanation of how patients can access care records and claims data through an available patient portal, if applicable, and how they can share access to their Blue Button® electronic health information with caregivers.

(D) Explanation of the type of beneficiary-identifiable claims data the TEAM participant may receive.

(E) A statement that all existing Medicare beneficiary protections continue to be available to the TEAM beneficiary. These include the ability to report concerns of substandard care to Quality Improvement Organizations or the 1-800-MEDICARE helpline.

(F) A list of the providers, suppliers, and ACOs with whom the TEAM participant has a sharing arrangement. This requirement may be fulfilled by the TEAM participant including in the detailed notification a Web address where beneficiaries may access the list.

(2) ***TEAM collaborator notice.*** A TEAM participant must require every TEAM collaborator to provide written notice to applicable TEAM beneficiaries of TEAM, including information on the quality and payment incentives under TEAM, and the existence of its sharing arrangement with the TEAM participant.

(i) With the exception of ACOs, PGPs, NPPGPs, and TGPs, a TEAM participant must require every TEAM collaborator that furnishes an item or service to a TEAM beneficiary during an episode to provide written notice to the beneficiary of TEAM, including basic information on the quality and payment incentives under TEAM, and the existence of the TEAM collaborator's sharing arrangement.

(A) The notice must be provided no later than the time at which the beneficiary first receives an item or service from the TEAM collaborator during an episode. In circumstances where, due to the patient's condition, it is not feasible to provide notification at such time, the notification must be provided to the beneficiary or his or her representative as soon as is reasonably practicable.

(B) The TEAM collaborator must be able to provide a list of all beneficiaries who received such a notice, including the date on which the notice was provided to the beneficiary, to CMS upon request.

(ii) A TEAM participant must require every PGP, NPPGP, or TGP that is a TEAM collaborator where a member of the PGP, member of the NPPGP, or member of the TGP furnishes an item or service to a TEAM beneficiary during an episode to provide written notice to the beneficiary of TEAM, including basic information on the quality and payment incentives under TEAM, and the existence of the entity's sharing arrangement.

(A)

(*1*) The notice must be provided no later than the time at which the beneficiary first receives an item or service from any member of the PGP, member of the NPPGP, or member of the TGP, and the required PGP, NPPGP, or TGP notice may be provided by that member respectively.

(*2*) In circumstances where, due to the patient's condition, it is not feasible to provide notice at such times, the notice must be provided to the beneficiary or his or her representative as soon as is reasonably practicable.

(B) The PGP, NPPGP, or TGP must be able to provide a list of all beneficiaries who received such a notice, including the date on which the notice was provided to the beneficiary, to CMS upon request.

(iii) A TEAM participant must require every ACO that is a TEAM collaborator where an ACO participant or ACO provider/supplier furnishes an item or service to a TEAM beneficiary during an episode to provide written notice to the beneficiary of TEAM, including basic information on the quality and payment incentives under TEAM, and the existence of the entity's sharing arrangement.

(A)

(*1*) The notice must be provided no later than the time at which the beneficiary first receives an item or service from any ACO participant or ACO provider/supplier and the required ACO notice may be provided by that ACO participant or ACO provider/supplier respectively.

(*2*) In circumstances where, due to the patient's condition, it is not feasible to provide notice at such times, the notice must be provided to the beneficiary or his or her representative as soon as is reasonably practicable.

(B) The ACO must be able to provide a list of all beneficiaries who received such a notice, including the date on which the notice was provided to the beneficiary, to CMS upon request.

(3) ***Discharge planning notice.*** A TEAM participant must provide the beneficiary with a written notice of any potential financial liability associated with non-covered services recommended or presented as an option as part of discharge planning, no later than the time that the beneficiary discusses a particular post-acute care option or at the time the beneficiary is discharged from an anchor procedure or anchor hospitalization, whichever occurs earlier.

(i) If the TEAM participant knows or should have known that the beneficiary is considering or has decided to receive a non-covered post-acute care service or other non-covered associated service or supply, the TEAM participant must notify the beneficiary in writing that the service would not be covered by Medicare.

(ii) If the TEAM participant is discharging a beneficiary to a SNF after an inpatient hospital stay, and the beneficiary is being transferred to or is considering a SNF that would not qualify under the SNF 3-day waiver in § 512.580, the TEAM participant must notify the beneficiary in accordance with paragraph (b)(3)(i) of this section that the beneficiary will be responsible for payment for the services furnished by the SNF during that stay, except those services that would be covered by Medicare Part B during a non-covered inpatient SNF stay.

(4) ***Access to records and retention.*** Lists of beneficiaries that receive notifications or notices must be retained, and access provided to CMS, or its designees, in accordance with § 512.586.

(c) ***Availability of services.***

(1) The TEAM participant and its downstream participants must continue to make medically necessary covered services available to beneficiaries to the extent required by applicable law. TEAM beneficiaries and their assignees retain their rights to appeal claims in accordance with part 405, subpart I of this chapter.

(2) The TEAM participant and its downstream participants must not take any action to select or avoid treating certain Medicare beneficiaries based on their income levels or based on factors that would render the beneficiary an “at-risk beneficiary” as defined at § 425.20 of this chapter.

(3) The TEAM participant and its downstream participants must not take any action to selectively target or engage beneficiaries who are relatively healthy or otherwise expected to improve the TEAM participant's or downstream participant's financial or quality performance.

(d) ***Descriptive TEAM materials and activities.***

(1) The TEAM participant and its downstream participants must not use or distribute descriptive TEAM materials and activities that are materially inaccurate or misleading.

(2) The TEAM participant and its downstream participants must include the following statement on all descriptive TEAM materials and activities: "The statements contained in this document are solely those of the authors and do not necessarily reflect the views or policies of the Centers for Medicare & Medicaid Services (CMS). The authors assume responsibility for the accuracy and completeness of the information contained in this document."

(3) The TEAM participant and its downstream participants must retain copies of all written and electronic descriptive TEAM materials and activities and appropriate records for all other descriptive TEAM materials and activities in a manner consistent with § 512.135(c).

(4) CMS reserves the right to review, or have a designee review, descriptive TEAM materials and activities to determine whether or not the content is materially inaccurate or misleading. This review takes place at a time and in a manner specified by CMS once the descriptive TEAM materials and activities are in use by the TEAM participant.

§ 512.584 Cooperation in model evaluation and monitoring.

The TEAM participant and its TEAM collaborators must comply with the requirements of § 403.1110(b) of this chapter and must otherwise cooperate with CMS' TEAM evaluation and monitoring activities as may be necessary to enable CMS to evaluate TEAM in accordance with section 1115A(b)(4) of the Act and to conduct monitoring activities under § 512.590, including producing such data as may be required by CMS to evaluate or monitor TEAM, which may include protected health information as defined in 45 CFR 160.103 and other individually-identifiable data.

§ 512.586 Audits and record retention.

(a) ***Right to audit.*** The Federal government, including CMS, HHS, and the Comptroller General, or their designees, has the right to audit, inspect, investigate, and evaluate any documents and other evidence regarding implementation of TEAM.

(b) ***Access to records.*** The TEAM participant and its TEAM collaborators must maintain and give the Federal government, including CMS, HHS, and the Comptroller General, or their designees, access to all such documents and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the implementation of TEAM, including without limitation, documents and other evidence regarding all of the following:

(1) The TEAM participant's and its downstream participants' compliance with the terms of TEAM.

(2) The accuracy of TEAM reconciliation payment amounts and repayment amounts.

(3) The TEAM participant's payment of amounts owed to CMS under TEAM.

(4) Quality measure information and the quality of services performed under the terms of TEAM.

(5) Utilization of items and services furnished under TEAM.

(6) The ability of the TEAM participant to bear the risk of potential losses and to repay any losses to CMS, as applicable.

(7) Patient safety.

(8) Other program integrity issues.

(c) ***Record retention.***

(1) The TEAM participant and its downstream participants must maintain the documents and other evidence described in paragraph (b) of this section and other evidence for a period of 6 years from the last payment determination for the TEAM participant under TEAM or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the TEAM participant at least 30 days before the normal disposition date; or

(ii) There has been a termination, dispute, or allegation of fraud or similar fault against the TEAM participant or its downstream participants, in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

(2) If CMS notifies the TEAM participant of the special need to retain records in accordance with paragraph (c)(1)(i) of this section or there has been a termination, dispute, or allegation of fraud or similar fault against the TEAM participant or its downstream participants described in paragraph (c)(1)(ii) of this section, the TEAM participant must notify its downstream participants of this need to retain records for the additional period specified by CMS.

§ 512.588 Rights in data and intellectual property.

(a) CMS may—

(1) Use any data obtained under §§ 512.584, 512.586, or 512.590 to evaluate and monitor TEAM; and

(2) Disseminate quantitative and qualitative results and successful care management techniques, including factors associated with performance, to other providers and suppliers and to the public. Data disseminated may include patient—

(i) De-identified results of patient experience of care and quality of life surveys, and patient; and

(ii) De-identified measure results calculated based upon claims, medical records, and other data sources.

(b) Notwithstanding any other provision of this part, for all data that CMS confirms to be proprietary trade secret information and technology of the TEAM participant or its downstream participants, CMS or its designee(s) will not release this data without the express written consent of the TEAM participant or its downstream participant, unless such release is required by law.

(c) If the TEAM participant or its downstream participant wishes to protect any proprietary or confidential information that it submits to CMS or its designee, the TEAM participant or its downstream participant must label or otherwise identify the information as proprietary or confidential. Such assertions are subject to review and confirmation by CMS prior to CMS' acting upon such assertions.

§ 512.590 Monitoring and compliance.

(a) ***Compliance with laws.*** The TEAM participant and each of its downstream participants must comply with all applicable laws and regulations.

(b) ***CMS monitoring and compliance activities.***

(1) CMS staff, or its approved designee, may conduct monitoring activities to ensure compliance by the TEAM participant and each of its downstream participants with the terms of TEAM under this subpart to—

(i) Understand TEAM participants' use of TEAM payments; and

(ii) Promote the safety of beneficiaries and the integrity of TEAM.

(2) Monitoring activities may include, without limitation, all of the following:

(i) Documentation requests sent to the TEAM participant and its downstream participants, including surveys and questionnaires.

(ii) Audits of claims data, quality measures, medical records, and other data from the TEAM participant and its downstream participants.

(iii) Interviews with members of the staff and leadership of the TEAM participant and its downstream participants.

(iv) Interviews with beneficiaries and their caregivers.

(v) Site visits to the TEAM participant and its downstream participants, performed in a manner consistent with paragraph (c) of this section.

(vi) Monitoring quality outcomes and clinical data, if applicable.

(vii) Tracking patient complaints and appeals.

(3) In conducting monitoring and oversight activities, CMS or its designees may use any relevant data or information including without limitation all Medicare claims submitted for items or services furnished to TEAM beneficiaries.

(c) ***Site visits.***

(1) In a manner consistent with § 512.584, the TEAM participant and its downstream participants must cooperate in periodic site visits performed by CMS or its designees in order to facilitate the evaluation of TEAM and the monitoring of the TEAM participant's compliance with the terms of TEAM.

(2) CMS or its designee provides, to the extent practicable, the TEAM participant or downstream participant with no less than 15 days advance notice of any site visit. CMS—

(i) Attempts, to the extent practicable, to accommodate a request for particular dates in scheduling site visits; and

(ii) Does not accept a date request from a TEAM participant or downstream participant that is more than 60 days after the date of the CMS initial site visit notice.

(3) The TEAM participant and its downstream participants must ensure that personnel with the appropriate responsibilities and knowledge associated with the purpose of the site visit are available during all site visits.

(4) CMS may perform unannounced site visits at the office of the TEAM participant and any of its downstream participants at any time to investigate concerns about the health or safety of beneficiaries or other patients or other program integrity issues.

(5) Nothing in this part shall be construed to limit or otherwise prevent CMS from performing site visits permitted or required by applicable law.

(d) ***Reopening of payment determinations.***

(1) CMS may reopen a TEAM payment determination on its own motion or at the request of a TEAM participant, within 4 years from the date of the determination, for good cause (as defined at § 405.986 of this chapter).

(2) CMS may reopen a TEAM payment determination at any time if there exists reliable evidence (as defined in § 405.902 of this chapter) that the determination was procured by fraud or similar fault (as defined in § 405.902 of this chapter).

(3) CMS's decision regarding whether to reopen a TEAM payment determination is binding and not subject to appeal.

(e) ***OIG authority.*** Nothing contained in the terms of TEAM limits or restricts the authority of the HHS Office of Inspector General or any other Federal government authority, including its authority to audit, evaluate, investigate, or inspect the TEAM participant or its downstream participants for violations of any Federal statutes, rules, or regulations.

§ 512.592 Remedial action.

(a) ***Grounds for remedial action.*** CMS may take one or more remedial actions described in paragraph (b) of this section if CMS determines that the TEAM participant or a downstream participant:

(1) Has failed to comply with any of the terms of TEAM, included in this subpart.

(2) Has failed to comply with any applicable Medicare program requirement, rule, or regulation.

(3) Has taken any action that threatens the health or safety of a beneficiary or other patient.

(4) Has submitted false data or made false representations, warranties, or certifications in connection with any aspect of TEAM.

(5) Has undergone a change in control that presents a program integrity risk.

(6) Is subject to any sanctions of an accrediting organization or a Federal, State, or local government agency.

(7) Is subject to investigation or action by HHS (including the HHS Office of Inspector General and CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including any of the following:

(i) Being subject to the filing of a complaint or filing of a criminal charge.

(ii) Being subject to an indictment.

(iii) Being named as a defendant in a False Claims Act qui tam matter in which the Federal government has intervened, or similar action.

(8) Has failed to demonstrate improved performance following any remedial action imposed under this section.

(9) Has misused or disclosed beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the TEAM data sharing agreement.

(b) ***Remedial actions.*** If CMS determines that one or more grounds for remedial action described in paragraph (a) of this section has taken place, CMS may take one or more of the following remedial actions:

(1) Notify the TEAM participant and, if appropriate, require the TEAM participant to notify its downstream participants of the violation.

(2) Require the TEAM participant to provide additional information to CMS or its designees.

(3) Subject the TEAM participant to additional monitoring, auditing, or both.

(4) Prohibit the TEAM participant from distributing TEAM payments, as applicable.

(5) Require the TEAM participant to terminate, immediately or by a deadline specified by CMS, its agreement with a downstream participant with respect to TEAM.

(6) Require the TEAM participant to submit a corrective action plan in a form and manner and by a date specified by CMS.

(7) Discontinue the provision of data sharing and reports to the TEAM participant.

(8) Recoup TEAM payments.

(9) Reduce or eliminate a TEAM payment otherwise owed to the TEAM participant.

(10) Such other action as may be permitted under the terms of this part.

§ 512.594 Limitations on review.

There is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for all of the following:

(a) The selection of models for testing or expansion under section 1115A of the Act.

(b) The selection of organizations, sites, or participants to test TEAM, including a decision by CMS to remove a TEAM participant or to require a TEAM participant to remove a downstream participant from TEAM.

(c) The elements, parameters, scope, and duration of testing or dissemination, including without limitation the following:

(1) The selection of quality performance standards for TEAM by CMS.

(2) The methodology used by CMS to assess the quality of care furnished by the TEAM participant.

(3) The methodology used by CMS to attribute TEAM beneficiaries to the TEAM participant, if applicable.

(d) Determinations regarding budget neutrality under section 1115A(b)(3) of the Act.

(e) The termination or modification of the design and implementation of TEAM under section 1115A(b)(3)(B) of the Act.

(f) Determinations about expansion of the duration and scope of TEAM under section 1115A(c) of the Act, including the determination that TEAM is not expected to meet criteria described in paragraph (a) or (b) of this section.

§ 512.595 Bankruptcy and other notifications.

(a) ***Notice of bankruptcy.*** If the TEAM participant has filed a bankruptcy petition, whether voluntary or involuntary, the TEAM participant must provide written notice of the bankruptcy to CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed, unless final payment has been made by either CMS or the TEAM participant under the terms of TEAM and all administrative or judicial review proceedings relating to any TEAM payments have been fully and finally resolved.

(1) The notice of bankruptcy must be sent by certified mail no later than 5 days after the petition has been filed and must contain a copy of the filed bankruptcy petition (including its docket number).

(2) The notice to CMS must be addressed to the CMS Office of Financial Management at 7500 Security Boulevard, Mailstop C3-01-24, Baltimore, MD 21244 or such other address as may be specified on the CMS website for purposes of receiving such notices.

(b) ***Notice of legal name change.*** A TEAM participant must furnish written notice to CMS within 30 days of any change in its legal name becomes effective. The notice of legal name change must meet all of the following:

(1) Be in a form and manner specified by CMS.

(2) Include a copy of the legal document effecting the name change, which must be authenticated by the appropriate State official.

(c) ***Notice of change in control.***

(1) A TEAM participant must furnish written notice to CMS in a form and manner specified by CMS at least 90 days before any change in control becomes effective.

(2) If CMS determines, in accordance with § 512.592(a)(5), that a TEAM participant's change in control would present a program integrity risk, CMS may—

(i) Take remedial action against the TEAM participant under § 512.160(b).

(ii) Require immediate reconciliation and payment of all monies owed to CMS by a TEAM participant that is subject to a change in control.

§ 512.596 Termination of TEAM or TEAM participant from model by CMS.

(a) ***Termination of TEAM.***

(1) CMS may terminate TEAM for reasons including, but not limited to, the following:

(i) CMS determines that it no longer has the funds to support TEAM.

(ii) CMS terminates TEAM in accordance with section 1115A(b)(3)(B) of the Act.

(2) If CMS terminates TEAM, CMS provides written notice to the TEAM participant specifying the grounds for termination and the effective date of such termination.

(b) ***Notice of a TEAM participant's termination from TEAM.*** If a TEAM participant receives notification that it has been terminated from TEAM and wishes to dispute the termination, it must provide a written notice to CMS requesting review of the termination within 10 calendar days of the notice.

(1) CMS has 30 days to respond to the TEAM participant's request for review.

(2) If the TEAM participant fails to notify CMS, the termination is deemed final.

Subpart F [Reserved]

Subpart G—Ambulatory Specialty Model (ASM)

Source: 90 FR 50022, Nov. 5, 2025, unless otherwise noted.

GENERAL

§ 512.700 Basis and scope of subpart.

(a) ***Basis.*** This subpart implements the test of the Ambulatory Specialty Model (ASM) under section 1115A of the Act.

(b) ***Scope.*** This subpart sets forth the following:

(1) The method for selecting ASM participants.

(2) The methodology for ASM participant performance assessment and scoring for purposes of the improvement activities ASM performance category, quality ASM performance category, cost ASM performance category, and Promoting Interoperability ASM performance category, including beneficiary inclusion and episode-based cost measures.

(3) Data submission for applicable ASM performance categories.

(4) The schedule and methodologies for payment adjustments.

(5) Appeals process.

(6) Data sharing with ASM participants.

(7) ASM beneficiary incentives.

(8) Collaborative care arrangements.

(9) Application of the CMS-sponsored model arrangements and patient incentives safe harbor.

(10) Medicare program waivers.

(11) Except as specifically noted in this subpart, the regulations under this subpart do not affect the applicability of other provisions affecting providers and suppliers under Medicare fee for service, including the applicability of provisions regarding payment, coverage, or program integrity.

(c) ***Applicability.*** Except as otherwise specified in this subpart, ASM participants are subject to the standard provisions for Innovation Center models specified in subpart A of this part 512 and in subpart K of part 403 of this chapter.

§ 512.705 Definitions.

For purposes of this part, the terms in this part have the same meanings as 42 CFR 512.110 and 414.1300 unless otherwise stated.

ASM beneficiary means a Medicare FFS beneficiary who is being treated by an ASM participant for a targeted chronic condition.

ASM cohort means a group of ASM participants who treat the same ASM targeted chronic condition, specifically the ASM heart failure cohort and the ASM back pain cohort.

ASM data sharing agreement means an agreement between the ASM participant, and CMS that includes the terms and conditions for any beneficiary-identifiable data being shared with the ASM participant under § 512.760(e).

ASM heart failure cohort refers to all ASM heart failure participants.

ASM heart failure participant means an ASM participant who meets the ASM participant eligibility criteria related to heart failure.

ASM incentive pool means a fixed percentage of the total amount of Medicare Part B covered professional services claims paid to ASM participants with final scores within an ASM cohort during an ASM performance year that would be distributed in the form of scaled payment adjustments during an ASM payment year. CMS calculates an ASM incentive pool for each ASM cohort for each ASM payment year as described at § 512.750(c)(1)(iii).

ASM low back pain cohort refers to all ASM low back pain participants.

ASM low back pain participant means an ASM participant who meets the ASM participant eligibility criteria related to low back pain.

ASM participant means an individual clinician who, for at least one ASM performance year, satisfies the ASM participant eligibility criteria and has been selected for participation in the model as described at § 512.710(g).

ASM participant eligibility criteria means the set of criteria defined at § 512.710(b) that CMS uses to determine whether a clinician is selected to participate in ASM.

ASM payment adjustment factor means a percent value based on an ASM participant's final score as described at § 512.750(c)(1) that CMS uses in calculating adjustments to the ASM participant's Medicare Part B payments for covered professional services during an ASM payment year.

ASM payment multiplier means the numerical value equal to 1 plus the ASM payment adjustment factor determined for an ASM participant for an applicable ASM payment year as described at § 512.750(c).

ASM payment year means a calendar year in which CMS applies the ASM payment multiplier to Medicare Part B payments for covered professional services based on the final score achieved by that ASM participant for the ASM performance year 2 years prior.

ASM performance category means a group of applicable measures or activities used to assess ASM participant's performance on quality, cost, improvement activities, or Promoting Interoperability.

ASM performance category score means the assessment of each ASM participant's performance on the applicable measures and activities for a performance category during an ASM performance year based on the performance standards described at §§ 512.715, 512.725, 512.730, 512.735, and 512.740.

ASM performance report means the notification that CMS provides to the ASM participant for each ASM performance year, which contains the information specified at § 512.745(b).

ASM performance year means a 12-month period beginning on January 1 and ending on December 31 of each year during the first 5 calendar years of ASM test period.

ASM redistribution percentage means a percentage of Medicare Part B covered professional services payments to ASM participants during an ASM performance year that CMS distributes in the form of payment adjustment to ASM participants during an ASM payment year as described at § 512.750(c)(1)(iii).

ASM risk level means the magnitude of the maximum positive or negative net payment adjustment percentage to which an ASM participant would be subject to during an ASM payment year as described at § 512.750(c)(1)(i).

ASM targeted chronic condition means a medical condition that is a core focus of ASM; that is, heart failure or low back pain.

ASM test period means the 7-year period from January 1, 2027, to December 31, 2033, that includes all ASM performance years and ASM payment years.

ASTP/ONC stands for the Assistant Secretary for Technology Policy/Office of the National Coordinator on Health Information Technology.

CY means calendar year.

CEHRT stands for Certified Electronic Health Records Technology that meets the requirements set forth in § 414.1305 of this chapter, except all instances of references to Merit-based Incentive Payment System (MIPS) are to be replaced with references to ASM.

Clinician has the same meaning as "eligible professional" as defined in section 1848(k)(3) of the Act, as identified by a unique TIN and NPI combination.

CMS EHR Certification ID means the identification number that represents the combination of Certified Health Information Technology that is owned and used by providers and hospitals to provide care to their patients and is generated by the Certified Health IT Product List.

Collaborative care arrangement means an arrangement that meets all of the requirements set forth in § 512.771.

Core Based Statistical Area (CBSA) means a statistical geographic area, based on the definition as identified by the Office of Management and Budget in the OMB Bulletin 23-01 issued on July 21, 2023, with a population of at least 10,000, which consists of a county or counties anchored by at least one core (urbanized area or urban cluster), plus adjacent counties having a high degree of social and economic integration with the core (as measured through commuting ties with the counties containing the core).

Covered entity has the meaning set forth at 45 CFR 160.103.

Covered professional services means "covered services" and has the meaning set forth in § 512.110 of this chapter.

CQM stands for Clinical Quality Measures.

Days means calendar days unless otherwise specified by CMS.

Dual eligible proportion means the share of a participant's beneficiaries who are dually eligible Medicare beneficiaries

Dually eligible Medicare beneficiary means a beneficiary enrolled in both Medicare and full Medicaid benefits.

EBCM stands for episode-based cost measure and means the standardized Medicare-allowed cost for the items and services furnished to a patient during an episode of care, based on FFS claims and Medicare Part D claims data.

eCQM stands for electronic clinical quality measures.

EHR stands for Electronic Health Record and means a "Base EHR," as defined at 45 CFR 170.102.

Exchange function means the function used to translate an ASM participant's final score into an ASM payment adjustment factor as described at § 512.750(c)(1)(ii)..

Episode means all the relevant health care services a patient receives during a specified period for the treatment of a physical or behavioral health condition.

FFS stands for fee-for-service.

Final score means a composite assessment (using a scoring scale of zero to 100) for each ASM participant for an ASM performance year determined using the methodology for assessing the total performance of an ASM participant according to performance standards for applicable measures and activities for each ASM performance category as described in § 512.745.

HCC risk score stands for Hierarchical Condition Category risk score and means the risk score assigned to a Medicare beneficiary in accordance with the HCC risk adjustment model established by CMS under section 1853(a)(1) of the Act.

Health-related social need means an unmet, adverse social condition that can contribute to poor health outcomes and is a result of underlying social determinants of health, which refer to the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.

Improvement activities mean activities relating to care coordination, integration of specialty and primary care, and addressing health-related social needs of patients.

Mandatory geographic area means a CBSA or metropolitan division as defined by the Office of Management and Budget and selected by CMS under the terms of § 512.710(f).

Meaningful EHR user means an ASM participant who possesses CEHRT, uses the functionality of CEHRT, reports on applicable objectives and measures specified for the Promoting Interoperability ASM performance category for a performance period in the form and manner specified by CMS, does not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of CEHRT, and engages in activities related to supporting providers with the performance of CEHRT.

Measure achievement points mean numerical values assigned to an ASM participant's reported performance data, that CMS uses to calculate an ASM performance category score.

Metropolitan division means—

(1) A county or group of counties (or equivalent entities) delineated within a larger metropolitan statistical area, provided that the larger metropolitan statistical area contains a single core with a population of at least 2.5 million and other criteria are met; and

(2) Consists of one or more main or secondary counties that represent an employment center or centers, plus adjacent counties associated with the main/secondary county or counties through commuting ties.

Metropolitan statistical area means the county or counties (or equivalent entities) associated with at least one urban area of at least 50,000 population, plus adjacent counties having a high degree of social and economic integration with the core as measured through commuting ties.

MIPS stands for the Merit-based Incentive Payment System.

NPI stands for National Provider Identifier.

ONC-ACB stands for ONC-Authorized Certification Bodies.

Physician has the meaning set forth in section 1861(r) of the Act.

Primary care services has the meaning set forth in section 1842(i)(4) of the Act.

Risk indicator refers to hierarchical condition category (HCC) risk scores under the HCC risk adjustment model established by CMS under section 1853(a)(1) of the Act or the proportion of beneficiaries with dual eligible status used in calculating the complex patient scoring adjustment as defined at § 512.745(a)(3).

SAFER stands for Safety Assurance Factors for EHR Resilience.

Scaling factor means a numerical value calculated by CMS to ensure that the total estimated payment adjustments in an ASM payment year are equal to the ASM incentive pool for the applicable ASM payment year as described at § 512.750(c)(1)(iv).

Small practice means a practice consisting of 15 or fewer clinicians at the time we identify ASM participants for an ASM performance year as described at § 512.710(g).

Specialty type means a medical specialty as determined by the specialty code indicated on the plurality of a clinician's Medicare Part B claims.

Solo practitioner means a practice consisting of 1 clinician at the time we identify ASM participants for an ASM performance year as described at § 512.710(g).

Submission type means the mechanism by which the ASM submitter submits data to CMS in the form and manner specified by CMS, including, but not limited to all of the following:

(1) Direct.

(2) Log in and upload.

(3) Log in and attest.

Third -party intermediary has the meaning set forth in § 414.1305 of this chapter.

TIN stands for Taxpayer Identification Number.

Topped out measure has the meaning of either topped out process measure or topped out non-process measure set forth in § 414.1305 of this chapter.

U.S. Territories has the meaning set forth in § 512.110 of this chapter.

[90 FR 50022, Nov. 5, 2025; 91 FR 12081, Mar. 12, 2026]

§ 512.710 Participant eligibility and selection.

(a) ***Mandatory ASM participation.***

(1) Unless otherwise specified, any clinician who meets all ASM participant eligibility criteria as specified in paragraph (b) of this section and furnishes covered services during any applicable ASM performance year within the ASM test period is considered an ASM participant for the duration of the model.

(i) 2027 ASM performance year: ASM participants—

(A) Are measured for performance and exempted from MIPS participation, if applicable, during CY 2027;

(B) Report and are scored during CY 2028; and

(C) Receive payment adjustments for CY 2027 performance in CY 2029.

(ii) 2028 ASM performance year: ASM participants—

(A) Meeting ASM eligibility criteria for the 2028 performance year are measured for performance and exempted from MIPS participation, if applicable, during CY 2028;

(B) Report and are scored during CY 2029; and

(C) Receive payment adjustments for CY 2028 performance in CY 2030.

(iii) 2029 ASM performance year: ASM participants—

(A) Meeting ASM eligibility criteria for the 2029 performance year are measured for performance and exempted from MIPS participation, if applicable, during CY 2029;

(B) Report and are scored during CY 2030; and

(C) Receive payment adjustments for CY 2029 performance in CY 2031.

(iv) 2030 ASM performance year: ASM participants—

(A) Meeting ASM eligibility criteria for the 2030 performance year are measured for performance and exempted from MIPS participation, if applicable, during CY 2030;

(B) Report and are scored during CY 2031; and

(C) Receive payment adjustments for CY 2030 performance in CY 2032.

(v) 2031 ASM performance year: ASM participants—

(A) Meeting ASM eligibility criteria for the 2031 performance year are measured for performance and exempted from MIPS participation, if applicable, during CY 2031;

(B) Report and are scored during CY 2032; and

(C) Receive payment adjustments for CY 2031 performance in CY 2033.

(2)

(i) For any ASM performance year within the ASM test period that an ASM participant does not meet the criteria for mandatory participation set forth in this section, the ASM participant is not subject, for the applicable ASM performance year, to §§ 512.715, 512.720, 512.745, and 512.750.

(ii) For a ASM performance year described in paragraph (a)(2)(i) of this section, the ASM participant is no longer eligible for the waivers as described at § 512.775 and is instead subject to MIPS reporting obligations, if applicable.

(b) ***ASM participant eligibility criteria.*** CMS uses the following set of criteria to determine whether a clinician is an ASM participant:

(1) Is a clinician who bills claims under the Medicare Physician Fee Schedule.

(2) Is identified by TIN/NPI as a selected specialty type as described in paragraph (d) of this section.

(3) Meets the EBCM episode volume threshold applicable to an ASM targeted chronic condition as described at paragraph (e) of this section.

(4) Is located in one of the mandatory geographic areas selected in accordance with paragraph (f) of this section.

(c) ***Participant exclusion due to change in TIN during an ASM performance year.***

(1) An ASM participant who stops assigning billing rights to the TIN used to identify the ASM participant and begins assigning billing rights to a new TIN during an applicable ASM performance year must notify CMS of the change in a form and manner determined by CMS within 30 days of the change.

(2)

(i) An ASM participant who notifies CMS of a change in TIN during an ASM performance year is not subject, for the applicable ASM performance year, to §§ 512.715, 512.720, 512.745, and 512.750.

(ii) The ASM participant described in paragraph (c)(2)(i) of this section is no longer eligible for the waivers as described at § 512.775 and is instead subject to MIPS reporting obligations, if applicable.

(d) ***Specialty type.*** ASM participants have one of the following Medicare Part B specialty codes indicated on the plurality of their Medicare Part B claims:

(1) Heart failure specialty type ¾

(i) Cardiology.

(ii) [Reserved]

(2) Low back pain specialty type ¾

(i) Anesthesiology.

(ii) Interventional Pain Management.

(iii) Neurosurgery.

(iv) Orthopedic Surgery.

(v) Pain Management.

(vi) Physical Medicine and Rehabilitation.

(e) ***EBCM episode volume.*** To determine if a clinician meets the ASM participant eligibility criterion defined in paragraph (b)(3) of this section, CMS uses the volume of EBCM episodes related to ASM targeted chronic conditions that are attributed to a clinician using the applicable EBCM specifications and attribution methodology.

(1) ***Heart failure EBCM.*** Clinicians who have a specialty designation type described at § 512.710(d)(1) and 20 or more heart failure EBCM episodes attributed in accordance with the heart failure episode-based cost measure as specified under MIPS during the calendar year 2 years prior to the applicable ASM performance year meet the ASM participant eligibility criterion defined in paragraph (b)(3) of this section.

(2) ***Low back pain EBCM.*** Clinicians who have a specialty designation type described at § 512.710(d)(2) and 20 or more low back pain EBCM episodes attributed in accordance with the low back pain episode-based cost measure as specified under MIPS during the calendar year 2 years prior to the applicable ASM performance year meet the ASM participant eligibility criterion defined in paragraph (b)(3) of this section.

(f) ***Mandatory geographic areas.*** CMS uses a stratified random sampling methodology described in paragraphs (f)(2) and (f)(3) of this section to select CBSA and metropolitan divisions (in cases where OMB divides large metropolitan statistical areas into metropolitan divisions) from which CMS identifies clinicians for participation in ASM.

(1) ***Exclusions.*** CMS excludes from the selection of CBSAs and metropolitan divisions applicable areas that meet any of criteria described in paragraph (f)(1)(i) or (ii) of this section.

(i) Areas that do not meet the criteria described in paragraphs (f)(1)(i)(A) and (f)(1)(i)(B) of this section:

(A) Have at least one clinician with a specialty designation type described at § 512.710(d)(1) with 20 or more heart failure EBCM episodes attributed between January 1, 2024 and December 31, 2024.

(B) Have at least one clinician with a specialty designation type described at § 512.710(d)(2) with 20 or more low back pain EBCM episodes attributed between January 1, 2024 and December 31, 2024.

(ii) Areas located entirely in U.S. Territories.

(2) ***CBSA and metropolitan division stratification process.*** Prior to sampling CBSAs and metropolitan divisions, CMS stratifies CBSAs and metropolitan divisions, excluding those described in paragraph (f)(1) of this section, into six mutually exclusive strata based on three CBSA/metropolitan division-level characteristics (average total Part A and Part B episode spending, volume of eligible episodes, and metropolitan division status) as described in paragraphs (f)(2)(i) through (vi) of this section. "Average total episode spending" as the term is used in paragraphs (f)(2)(i) through (vi) of this section, is measured using the average total Part A and Part B episode spending using claims data from January 1, 2024 to December 31, 2024 relating to heart failure and low back pain episodes, as specified under the episode-based cost measures described in § 512.710(e). Values below the median are characterized as "Low" average total episode spending. Values at or above the median are characterized as "High" average total spending. "Eligible episode volume" as the term is used in paragraphs (f)(2)(i) through (vi) of this section, is measured as the total count of eligible heart failure and low back pain episodes, as specified under the episode-based cost measures described in § 512.710(e), in a CBSA between January 1, 2024 and December 31, 2024. CMS categorizes CBSAs with values below the median as "Low;" CBSAs at-or-above the median and below the 95th percentile as "High;" and CBSAs at-or-above the 95th percentile as "Very High.".

(i) CBSAs with "Low" average total episode spending and "Low" eligible episode volume.

(ii) CBSAs with "Low" average total episode spending and "High" eligible episode volume.

(iii) CBSAs with "High" average total episode spending (as defined below) and "Low" eligible episode volume.

(iv) Eligible CBSAs with "High" average total episode spending and "High" eligible episode volume.

(v) Eligible CBSAs with "Very High" eligible episode volume.

(vi) Eligible metropolitan divisions.

(3) ***Sampling of CBSAs and metropolitan divisions.*** CMS selects approximately 40 percent of CBSAs and metropolitan divisions from each stratum to select the mandatory geographic areas. If 40 percent of a given stratum does not result in a whole number of CBSAs or metropolitan divisions, CMS rounds up to the next whole number to ensure that at least 40 percent of areas from each stratum are selected.

(4) ***Assignment of CBSA or metropolitan division code to clinicians.*** CMS assigns a CBSA or a metropolitan division code to every TIN/NPI with attributed EBCM episodes related to ASM targeted chronic conditions for the applicable calendar year as described in paragraph (e) of this section to determine ASM participation eligibility for an applicable ASM performance year:

(i) CMS assigns each attributed EBCM episode a ZIP Code, which represents the service location where the attributed TIN/NPI encounters the beneficiary attributed to the episode the most, based on the plurality of Part B claims used to construct the episode. If the ZIP Codes representing service location where the attributed TIN/NPI appears in equal number in the Part B claims used to construct the episode, then CMS assigns the ZIP Code based on the ZIP Code that represents the Part B claim with—

(A) The highest total cost indicated by the total standardized allowed amount; or

(B) Most recent date.

(ii) CMS assigns each attributed EBCM episode a CBSA or metropolitan division code based on the ZIP Code assigned to the episode as described in paragraph (f)(4)(i) of this section. If the ZIP Code assigned to the EBCM episode is in multiple CBSAs or metropolitan divisions, then CMS assigns the EBCM episode the CBSA or metropolitan division code where the ZIP Code has the highest proportion of—

(A) Total addresses; or

(B) Business addresses.

(iii) CMS assigns each TIN/NPI combination a single CBSA or metropolitan division code based on the most common CBSA or metropolitan division code assigned to episodes attributed to the TIN/NPI as described in paragraph (f)(4)(ii) of this section. If the TIN/NPI has equal number of episodes across multiple CBSAs or metropolitan divisions, then CMS assigns the TIN/NPI a CBSA or metropolitan division with the CBSA or metropolitan division that has either of the following:

(A) The highest total risk-adjusted episode spending across all episodes assigned to the CBSA or metropolitan division.

(B) Episodes with more recent dates.

(g) ***Selection and notification process for ASM participants.*** For each ASM performance year, CMS identifies all clinicians furnishing covered services using the ASM participant eligibility criteria specified in paragraph (b) of this section and applicable data from 2 calendar years prior to each ASM performance year. Any clinician selected for participation for any year of the model is considered an ASM participant for the remainder of the ASM test period.

(1) ***2027 ASM performance year only*** —

(i) ***Preliminarily eligible ASM participants.*** Using applicable data from calendar year 2024, CMS identifies all clinicians who meet the ASM participant eligibility criteria for participation starting in the 2027 ASM performance year/2029 ASM payment year. The clinicians identified as preliminarily eligible ASM participants are made public in a form and manner determined by CMS.

(ii) ***Final ASM participants.*** CMS identifies the final ASM participants selected for participation starting in the 2027 ASM performance year/2029 ASM payment year by confirming that the preliminarily eligible ASM participants identified under paragraph (g)(1)(i) of this section meet the ASM participant eligibility criteria using applicable data from CY 2025. The clinicians selected as ASM participants starting in the 2027 ASM performance year/2029 ASM payment year is made public in a form and manner determined by CMS.

(2) ***2028 ASM performance year and subsequent years.***

(i) Beginning with the 2028 ASM performance year/2030 ASM payment year, CMS determines if the previously selected ASM participants continue to meet the ASM participant eligibility criteria for the upcoming ASM performance year/ASM payment year using applicable data from the calendar year 2 years prior to the applicable ASM performance year. An ASM participant who does not meet the ASM participant eligibility criteria for the upcoming ASM performance year/ASM payment year is not subject to provisions described at §§ 512.715, 512.720, and 512.745 and must, if applicable, participate in MIPS. The final ASM participants selected for participation for each applicable ASM performance year is made public in a form and manner determined by CMS.

(ii) Beginning with the 2028 ASM performance year/2030 ASM payment year and prior to the start of each ASM performance year, CMS determines if additional clinicians not previously identified as ASM participants meet the ASM participant eligibility criteria for the upcoming ASM performance year/ASM payment year using applicable data from the calendar year 2 years prior to the applicable ASM performance year. The final ASM participants selected for participation for each applicable ASM performance year is made public in a form and manner determined by CMS.

[90 FR 50022, Nov. 5, 2025; 91 FR 12081, Mar. 12, 2026]

Performance Categories and Scoring

§ 512.715 Overview of performance assessment.

(a) ***General.*** As further described in §§ 512.725, 512.730, 512.735, and 512.740:

(1) An ASM participant receives a specific number of points for its performance on each measure or activity within an ASM performance category.

(2) CMS assigns the total amount of points an ASM participant may receive for its performance on a measure or activity.

(3) CMS calculates a final score as described at § 512.745 using the points received across all four ASM performance categories.

(b) ***Data sources.***

(1) CMS uses Medicare claims data and Medicare administrative data reported to calculate measure scores included in the quality and cost ASM performance categories under §§ 512.725 and 512.730.

(2) CMS uses model-specific data reported under § 512.720 to calculate applicable measure or activity scores for the quality, improvement activities, and Promoting Interoperability ASM performance categories under §§ 512.725, 512.735, and 512.740.

§ 512.720 Data submission requirements.

(a) ***Applicable performance categories and data submission requirements.***

(1) Except as provided in paragraph (a)(2) of this section, as applicable, ASM participants must submit data on measures and activities for the quality, improvement activities, and Promoting Interoperability ASM performance categories described in §§ 512.725(b) and (c), 512.735(b), and 512.740 in accordance with this section. The data may also be submitted on behalf of the ASM participant by a third-party intermediary.

(i) For the quality ASM performance category, a data submission must—

(A) Include numerator and denominator data for at least one applicable quality measure described in § 512.725(b) or (c) that is not an administrative claims-based collection type and meets the data completeness requirement as specified at § 512.725(f) and

(B) Be submitted at the TIN/NPI level, unless the ASM participant is excepted under paragraph (f) of this section.

(ii) For the improvement activities ASM performance category, a data submission must—

(A) Include an attestation of meeting the specifications of each required improvement activity described in § 512.735(c); and

(B) Be submitted at the TIN level;

(iii) For the Promoting Interoperability ASM performance category, a data submission must do all of the following:

(A) Include all of the following elements:

(*1*) Performance data, including any claim of an applicable exclusion, for the measures in each objective, as specified by CMS at § 512.740(b).

(*2*) Required attestation statements, as specified by CMS at § 512.740(b).

(*3*) CMS EHR Certification ID (CEHRT ID) from the Certified Health IT Product List (CHPL).

(*4*) The start date and end date for the applicable performance period as set forth in § 512.740(a).

(B) Be submitted at the TIN level.

(2) There are no data submission requirements for the cost ASM performance category measures and activities described under § 512.730(b) or administrative claims-based quality measures as described in § 512.725(b) or (c). Performance in the cost ASM performance category and administrative claims-based quality measures are calculated by CMS using administrative claims data, which includes claims submitted with dates of service during the applicable performance period that are processed no later than 60 days following the close of the applicable performance period.

(b) ***Data submission types for ASM participants.*** An ASM participant must submit their data using the following:

(1) For the quality ASM performance category, the direct and login and upload submission types.

(2) For the improvement activities and Promoting Interoperability ASM performance categories, the direct, login and upload, or login and attest submission types.

(c) ***Use of multiple data submission types.*** ASM participants may submit their data using multiple data submission types for any ASM performance category described in paragraph (a)(1) of this section provided that the ASM participant uses the same identifier for all ASM performance categories and all data submissions.

(d) ***Data submission deadlines.*** The data submission deadline is March 31st of the calendar year following the close of the applicable ASM performance year or a later date as specified by CMS for the direct, login and upload, and login and attest submission types.

(e) ***Treatment of multiple data submissions.***

(1)

(i) For multiple data submissions received in the quality and improvement activities ASM performance categories in accordance with paragraphs (a)(1)(i) and (ii) of this section for an individual ASM participant from submitters in multiple organizations (for example, qualified registry, practice administrator, or EHR vendor), CMS calculates and scores each submission received and assign the highest of the scores.

(ii) For multiple data submissions received for an individual ASM participant from one or multiple submitters in the same organization, CMS scores the most recent submission.

(2) For multiple data submissions received for the Promoting Interoperability ASM performance category in accordance with paragraph (a)(1)(iii) of this section, CMS calculates a score for each data submission received and assigns the highest of the scores.

(f) ***Small practice quality measures submission.*** ASM participants who are part of a small practice may report quality measures in the quality ASM performance category at the TIN level.

§ 512.725 Quality ASM performance category.

(a) ***ASM performance year for quality measures.*** Beginning with 2029 ASM payment year, the ASM performance year for quality measures is the full calendar year from January 1 to December 31 that occurred 2 years prior to the applicable ASM payment year, except as otherwise specified for administrative claims-based measures.

(b) ***Quality measures for ASM heart failure cohort.*** CMS uses the following quality measures, as specified by CMS for the MIPS quality performance category unless otherwise stated, to assess performance for ASM heart failure participants in the quality ASM performance category:

(1) Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure for the Merit-based Incentive Payment System (MIPS Q492) with minor modification to the measure specifications to attribute solely to ASM participants who have had one (1) or more visits with the beneficiary.

(2) Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) (MIPS Q008).

(3) Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD) (MIPS Q005).

(4) Controlling High Blood Pressure (MIPS Q236).

(5) Functional Status Assessments for Heart Failure (MIPS Q377).

(c) ***Quality measures for ASM low back pain cohort.*** CMS uses the following quality measures, as specified by CMS for the MIPS quality performance category unless otherwise stated, to assess performance for ASM low back pain participants in the quality ASM performance category:

(1) Use of High-Risk Medications in Older Adults (MIPS Q238).

(2) Preventive Care and Screening: Screening for Depression and Follow-Up Plan (MIPS Q134).

(3) Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (MIPS Q128).

(4) Functional Status Change for Patients with Low Back Impairments (MIPS Q220).

(d) ***Removal, addition, and maintenance of technical specifications of quality measures.*** CMS uses notice-and-comment rulemaking to communicate any updates or changes to the quality measure sets described in paragraphs (b) and (c) of this section.

(e) ***Data submission criteria for the quality ASM performance category.***

(1) CMS uses quality measures as described in paragraphs (b) and (c) of this section with the following data collection types:

(i) MIPS CQMs.

(ii) eCQMs.

(iii) Administrative claims-based.

(2) ***Data submission requirements.***

(i) An ASM heart failure participant must submit data on all quality measures specified in paragraph (b) of this section using MIPS CQMs or eCQMs.

(ii) An ASM low back pain participant must submit data on all quality measures specified in paragraph (c) of this section using MIPS CQMs or eCQMs, unless otherwise stated.

(iii) For eCQMs, the submission of data requires the utilization of CEHRT, as defined at § 414.1305.

(3) An ASM participant is not required to submit data for the calculation of administrative claims-based measures so long as data submission requirements as specified at § 512.720(a)(1)(i) are met.

(f) ***Data completeness requirement for the quality ASM performance category.***

(1) Except as specified at paragraph (e)(3) of this section and for each required measure specified in paragraphs (b) or (c) of this section, ASM participants must submit data on at least 75 percent of the ASM participant's patients that meet the measure's denominator criteria, regardless of payer.

(2) ASM participants receive zero measure achievement points for each measure required in paragraphs (b) or (c) of this section that does not meet the data completeness requirement, as specified at paragraph (f)(1) of this section.

(3) CMS excludes from an ASM's participant total measure achievement points and total available measure achievement points any measures required under paragraphs (b) or (c) of this section that meet the respective measure's data completeness requirement, but do not have a benchmark.

(g) ***Minimum case requirements.***

(1) Unless otherwise specified by CMS, the minimum case requirement for each quality measure required in paragraphs (b) or (c) of this section is 20 cases.

(2) CMS excludes from an ASM's participant total measure achievement points and total available measure achievement points any measures required under paragraphs (b) or (c) of this section that meet the respective measure's data completeness requirement as specified at paragraph (f)(1) of this section but do not meet the measure's case minimum requirement as specified at paragraph (g)(1) of this section.

(h) ***Quality measure achievement points and quality ASM performance category scoring.*** Unless a different scoring weight is assigned by CMS, performance in the quality ASM performance category comprises of 50 percent of a ASM participant's final score for each ASM payment year.

(1) ***Measure achievement points.***

(i) For each ASM performance year, ASM participants receive between 1 and 10 measure achievement points (including partial points) for each required measure as specified in paragraphs (b) or (c) of this section on which data is submitted in accordance with paragraph (e) of this section that does all of the following:

(A) Has a benchmark specified in paragraph (h)(2) of this section.

(B) Meets the case minimum requirements specified in paragraph (g) of this section.

(C) Meets the data completeness criteria specified in paragraph (f) of this section.

(D) For each administrative claims-based measure with a benchmark as described at paragraph (h)(2)(iii) of this section and meets the case minimum requirement at paragraph (g) of this section.

(ii) The number of ASM measure achievement points received for each measure is determined based on the applicable benchmark decile category and the percentile distribution.

(iii) ASM participants receive zero ASM measure achievement points for each measure required in paragraphs (b) or (c) of this section on which no data is submitted in accordance with § 512.720.

(iv) ASM participants who submit data in accordance with paragraphs (e) through (g) of this section on a single required measure via multiple applicable collection types are scored only on the data submission with the greatest number of measure achievement points.

(2)

(i) ***Benchmarks.*** Except as provided in paragraph (h)(2)(iii) of this section, CMS bases benchmarks on an ASM participant's performance by collection type, from one following data sources:

(A) Reported by ASM participants, to the extent feasible, during the ASM performance year.

(B) A previous ASM performance year, if available.

(C) Another period determined by CMS.

(ii) Each benchmark must have a minimum of 20 ASM participants who reported the measure having met the following criteria:

(A) The case minimum requirements in paragraph (g) of this section.

(B) The data completeness requirement as specified in paragraph (f) of this section.

(C) A performance rate that is greater than zero.

(iii) CMS calculates a benchmark for an administrative claims quality measure using the performance on the measure during the current ASM performance year.

(iv) CMS determines a benchmark using decile categories based on the applicable period of data used to determine the measure's benchmark.

(3) ***Topped out measures.*** CMS identifies topped out measures in the benchmarks for each ASM performance year based on within-model performance on each measure.

(4) ***Calculation of the quality ASM performance category score.***

(i) Unless otherwise specified by CMS, an ASM participant's quality ASM performance category score is the sum of all measure achievement points assigned for the applicable measures for the quality ASM performance category.

(A) The sum is divided by the total available measure achievement points.

(B) The quality ASM performance category score cannot exceed 100 percentage points.

(ii) For each measure that is submitted, if applicable, and impacted by significant changes or errors prior to the applicable data submission deadline at § 512.720(d), performance is based on data for 9 consecutive months of the applicable ASM performance year.

(A) Significant changes or errors means changes to or errors in a measure that are outside the control of the clinician and its agents and that CMS determines may result in patient harm or misleading results. Significant changes or errors include, but are not limited to the following:

(*1*) Changes to codes (such as ICD-10, CPT, or HCPCS codes) or the active status of codes.

(*2*) The inadvertent omission of codes or inclusion of inactive or inaccurate codes.

(*3*) Changes to clinical guidelines or measure specifications.

(B) CMS publishes a list of all measures scored in a form and manner specified by CMS.

(C) If the data are not available or CMS determines that they may result in patient harm or misleading results, the measure is excluded from an ASM participant's total measure achievement points and total available measure achievement points.

(iii) An ASM participant does not receive a quality ASM performance category score if the ASM participant meets the quality ASM performance category data submission requirements specified at § 512.720(a)(1)(i) but does not meet the case minimum requirements specified in paragraph (g) of this section for any required quality ASM performance category measure specified in paragraphs (b) or (c) of this section, as applicable, that has a benchmark as specified in paragraph (h)(2) of this section.

[90 FR 50022, Nov. 5, 2025; 91 FR 12081, Mar. 12, 2026]

§ 512.730 Cost ASM performance category.

(a) ***ASM performance year for cost performance measures.*** Beginning with the 2029 ASM payment year, the ASM performance year for cost measures is the full calendar year from January 1 to December 31 that occurred 2 years prior to the applicable ASM payment year.

(b) ***Cost measures.*** For purposes of assessing performance of ASM participants on the cost ASM performance category, CMS—

(1) For ASM heart failure participants, assess and score the participants on the Heart Failure EBCM (COST_HF_1), as specified under MIPS.

(2) For ASM low back pain participants, assess and score the participants on the Low Back Pain EBCM (COST_LBP_1), as specified under MIPS.

(c) ***Adding or removing*** cost *measures.* CMS may add new cost measures to, or remove existing cost measures from, the cost ASM performance category through notice and comment rulemaking.

(d) ***Minimum case requirements.*** Unless otherwise specified by CMS, the minimum case requirement for each cost measure is 20 cases.

(1) Each cost measure is attributed at the TIN/NPI level according to the measure specification for the applicable ASM performance year.

(2) An ASM participant must meet the minimum case volume to be scored on a cost measure.

(e) ***Cost measure achievement points and cost ASM performance category scoring.*** Unless a different scoring weight is assigned by CMS, performance in the cost ASM performance category comprises 50 percent of an ASM participant's final score for each ASM performance year.

(1) ***ASM measure achievement points.***

(i) For each cost measure attributed to an ASM participant, the ASM participant receives one to ten achievement points (including partial points) based on the ASM participant's performance on the cost measure during the ASM performance year compared to the cost measure's benchmark.

(ii) Achievement points are awarded based on which benchmark range the ASM participant's performance on the measure is in.

(2) ***Benchmarks***

(i) CMS bases cost measure benchmarks on cost measure performance during the ASM performance year.

(A) Each benchmark must have a minimum of 20 ASM participants who meet the minimum case volume specified in paragraph (d) of this section for CMS to determine a benchmark for the cost measure.

(B) If a benchmark is not determined for a cost measure, then the measure is not scored.

(ii) CMS determines 10 benchmark ranges based on the median cost of all ASM participants attributed the measure, plus or minus standard deviations. CMS awards achievement points based on which benchmark range an ASM participant's measure score corresponds.

(3) ***Calculation of the cost ASM performance category score.*** Except as otherwise specified in paragraph (e)(3)(i) of this section, the cost ASM performance category score is the sum of the total number of achievement points earned by the ASM participant divided by the total number of available achievement points, not to exceed 100 percent.

(i) An ASM participant does not receive a cost ASM performance category score if the ASM participant is not attributed the required cost measure for the ASM performance year specified in paragraph (b) of this section because the ASM participant has not met the case minimum specified in paragraph (d) of this section for the required cost measure or if a benchmark has not been created for a required cost measure as specified in paragraph (e)(2) of this section.

(ii) If data used to calculate a score for a cost measure are impacted by significant changes or errors affecting the ASM performance year, such that calculating the cost measure score would lead to misleading or inaccurate results, then the affected cost measure is excluded from the ASM participant's cost ASM performance category score and a cost ASM performance category score is not calculated.

(A) Significant changes or errors means changes to or errors in a measure that are outside the control of the clinician and its agents, and that CMS determines may result in patient harm or misleading results.

(B) Significant changes or errors include, but are not limited to, changes to codes (such as ICD-10, CPT, or HCPCS codes) or the active status of codes, the inadvertent omission of codes or inclusion of inactive or inaccurate codes, or changes to clinical guidelines or measure specifications.

(C) CMS empirically assesses the affected cost measure to determine the extent to which the changes or errors impact the calculation of a cost measure score such that calculating the cost measure score would lead to misleading or inaccurate results that negatively impact the measure's ability to reliably assess performance.

[90 FR 50022, Nov. 5, 2025; 91 FR 12081, Mar. 12, 2026]

§ 512.735 Improvement activities ASM performance category.

(a) ***ASM performance year for improvement activities.*** Beginning with the 2029 ASM payment year, the ASM performance year for improvement activities is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable ASM payment year, up to and including the full calendar year.

(b) ***Improvement activities.*** CMS uses the improvement activities specified in paragraph (c) of this section to evaluate performance of ASM participants in the improvement activities ASM performance category.

(c) ***Improvement activities specifications*** —

(1) ***Improvement Activity 1 (IA-1): Connecting to Primary Care and Ensuring Completion of Health-Related Social Needs Screening.*** An ASM participant must have evidence of processes, workflows, or technology that require the ASM participant to do all of the following:

(i) Confirm the ASM beneficiary has access to primary care services and, if not, assist the ASM beneficiary in finding a clinician who provides primary care services.

(ii) Communicate relevant information back to the ASM beneficiary's primary care provider following the ASM beneficiary's visit with the ASM participant.

(iii) Determine whether the ASM beneficiary has received an annual health-related social needs screening in the primary care setting and, if not, encourage the primary care services provider to conduct the screening or allow the ASM participant to conduct the health-related social needs screening.

(2) ***Improvement Activity 2 (IA-2): Establishing Communication and Collaboration Expectations with Primary Care using Collaborative Care Arrangements.*** An ASM participant must do all of the following:

(i) Have at least one executed collaborative care arrangement between a primary care practice with which the ASM participant shares ASM beneficiaries.

(ii) The collaborative care arrangement must include collaborative efforts related to at least three of the following five elements:

(A) Data sharing, which includes setting expectations for bi-directional sharing of patient information between the parties to the collaborative care arrangement, including but not limited to test results, treatment plans, and follow-up recommendations.

(B) Co-management, which includes defining co-management approaches, where the parties to the collaborative care arrangement work together to furnish complementary care for patients with complex or chronic conditions.

(C) Transitions in care planning, which includes defining protocols for seamless transitions of care between ASM participants, the primary care practice, or different care settings.

(D) Closed-loop communication, such as clearly articulated processes enforcing parameters on how ASM beneficiaries may be referred between the parties to the collaborative care arrangement.

(E) Care coordination integration comprised of structured processes to embed care coordination processes into the ASM participant's practice workflow.

(d) ***Scoring for improvement activities ASM performance category*** —

(1) ***ASM measure achievement points.*** ASM participants receive 10 ASM measure achievement points for attesting "yes" for each improvement activity specified in paragraph (c) in compliance with the data submission requirements at § 512.720.

(2) ***Calculation of the improvement activities ASM performance category score.*** Unless otherwise specified by CMS, CMS sums the total achievement points for all submitted improvement activities and divides this sum by the total number of available achievement points for the required improvement activities as specified in paragraph (c) of this section, not to exceed 100 percent.

§ 512.740 Promoting Interoperability ASM performance category.

(a) ***ASM performance year for the Promoting Interoperability ASM performance category.*** Beginning with the 2029 ASM payment year, the ASM performance year for Promoting Interoperability measures is the minimum of a continuous 180-day period within the calendar year that occurs 2 years prior to the applicable ASM payment year, up to and including the full calendar year.

(b) ***Reporting for the Promoting Interoperability ASM performance category.*** To earn an ASM performance category score greater than zero for the Promoting Interoperability ASM performance category for inclusion in the final score, an ASM participant must be a meaningful EHR user and meet the following criteria:

(1) ***CEHRT.*** Use CEHRT as defined at § 414.1305 for the ASM performance year.

(2) ***ASM Promoting Interoperability objectives and measures.*** Report on the following MIPS Promoting Interoperability measures, as specified by CMS through rulemaking:

(i) An ASM Participant must report both of the following measures or claim an exclusion or exclusions to fulfill the e-Prescribing objective:

(A) e-Prescribing (Measure ID #: PI_EP_1).

(B) Query of PDMP (Measure ID # PI_EP_2).

(ii) An ASM Participant must fulfill the Health Information Exchange objective through one of the following three options:

(A) Report the Support Electronic Referral Loops by Sending Health Information (Measure ID # PI_HIE_1) and Support Electronic Referral Loops by Receiving and Reconciling Health Information (Measure ID # PI_HIE_4).

(B) Health Information Exchange (HIE) Bi-Directional Exchange (Measure ID # PI_HIE_5).

(C) Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) (Measure ID # PI_HIE_6).

(iii) An ASM Participant must fulfill the Provider to Patient Exchange objective by reporting the Provide Patients Electronic Access to Their Health Information measure (Measure ID # PI_PEA_1).

(iv) An ASM Participant must fulfill the Public Health and Clinical Data Exchange objective by reporting both measures:

(A) Immunization Registry Reporting (Measure ID # PI_PHCDDR_1).

(B) Electronic Case Reporting (Measure ID PI_PHCDRR_3).

(3) ***Reporting ASM Promoting Interoperability objectives and measures.*** Comply with the following reporting requirements:

(i) For each measure under paragraph (b)(2) of this section, report—

(A) The numerator (of at least one) and denominator;

(B) Yes/no statement; or

(C) An exclusion that includes an option for the exclusion.

(ii) Report that the ASM participant completed the actions included in the MIPS Promoting Interoperability Security Risk Analysis measure (Measure ID # PI_PPHI_1) within the calendar year of the ASM performance year.

(iii) Submit an affirmative attestation regarding the ASM participant's completion of the annual self-assessment checklist under the MIPS Promoting Interoperability High Priority Practices Guide of the SAFER Guides measure (Measure ID # PI_PPHI_2) within the calendar year of the ASM performance year.

(4) ***Supporting use of CEHRT.*** ASM participants must support the use of CEHRT by fulfilling the following requirements:

(i) ***Supporting the use and performance of CEHRT.*** To fulfill ASM requirements to engage in activities related to supporting clinicians with the performance of CEHRT, the ASM participant:

(A) Must attest by providing all of the following:

(*1*) Acknowledgement of the requirement to cooperate in good faith with ONC direct review of the ASM participant's health information technology certified under the ONC Health IT Certification Program if a request to assist in ONC direct review is received.

(*2*) If requested, cooperation in good faith with ONC direct review of the ASM participant's health information technology certified under the ONC Health IT Certification Program as authorized by 45 CFR part 170, subpart E, to the extent that the technology meets, or can be used to meet, the definition of CEHRT, including by permitting timely access to the technology and demonstrating its capabilities as implemented and used by the ASM participant in the field.

(B) May attest to the following objectives and measures:

(*1*) Acknowledgement of the option to cooperate in good faith with ONC-ACB surveillance of his or her health information technology certified under the ONC Health IT Certification Program if a request to assist in ONC-ACB surveillance is received.

(*2*) If requested, cooperation in good faith with ONC-ACB surveillance of the ASM participant's health information technology certified under the ONC Health IT Certification Program as authorized by 45 CFR part 170, subpart E, to the extent that the technology meet, or can be used to meet, the definition of CEHRT, including by permitting timely access to the technology and demonstrating its capabilities as implemented and used by the ASM participant in the field.

(ii) Actions to limit or restrict the compatibility or interoperability of CEHRT. To fulfill ASM requirements for activities related to limiting or restricting the compatibility or interoperability of CEHRT, the ASM participant must not knowingly and willfully take action, such as to disabling functionality, to limit or restrict the compatibility or interoperability of CEHRT.

(c) ***Scoring the Promoting Interoperability ASM performance category*** —

(1) ***ASM measure achievement points.***

(i) An ASM participant earns a score for each measure by fulfilling the reporting requirements specified at paragraph (b) of this section. Score amounts are set forth in the MIPS measure specifications.

(ii) If an exclusion is reported for a measure, the points available for that measure are redistributed to another measure as set forth in the MIPS measure specifications.

(2) ***Promoting Interoperability ASM performance category score.*** Unless otherwise specified by CMS, CMS sums the scores for each of the required measures and divides this sum by the total number of available Promoting Interoperability points. The Promoting Interoperability ASM performance category score cannot exceed 100 percent.

§ 512.745 Final scoring.

(a) ***Final score calculation.*** CMS calculates a final score of zero to 100 points using the formula specified at paragraph (a)(5) of this section for each ASM participant that meets the requirements to receive a final score as specified in paragraph (a)(2) of this section.

(1) ***ASM performance category weights and scoring adjustments.*** CMS calculates the final score using the ASM performance category weights and scoring adjustments as follows:

(i) Quality ASM performance category weight is 50 percent.

(ii) Cost ASM performance category weight is 50 percent.

(iii) The improvement activities ASM performance category has a scoring adjustment that is applied to the final score without weighting.

(A) ASM participants that achieve a 100 percent score for the improvement activities ASM performance category do not receive an improvement activities ASM performance category scoring adjustment to final score.

(B) ASM participants that receive a 50 percent improvement activities ASM performance category score receive an improvement activities ASM performance category scoring adjustment of negative 10 points to the final score.

(C) ASM participants that receive a zero percent improvement activities ASM performance category score receive an improvement activities ASM performance category scoring adjustment of negative 20 points to the final score.

(iv) The Promoting Interoperability ASM performance category has a scoring adjustment that is applied to the final score without weighting.

(A) To determine the Promoting Interoperability ASM performance category scoring adjustment as described in paragraph (a)(1)(iv) of this section, the Promoting Interoperability ASM performance category score is multiplied by 100, the product is then subtracted from 100 and divided by the maximum negative Promoting Interoperability ASM performance category scoring adjustment of 10 points.

(B) The maximum Promoting Interoperability ASM performance category scoring adjustment is negative 10 points.

(2) ***Requirements to receive a final score.*** Except as described at § 512.780(c)(1), CMS determines whether an ASM participant receives a final score for the applicable ASM performance year depending on the data submitted by the ASM participant.

(i) Except as described in paragraph (a)(2)(iii) of this section, CMS calculates a final score greater than zero but not exceeding 100 as described in paragraph (a) of this section for the applicable ASM performance year for all ASM participants that meet the quality ASM performance category data submission requirements as specified at § 512.720(a)(1)(i).

(ii) CMS assigns a final score of zero for the applicable ASM performance year to all ASM participants who do not meet the quality ASM performance category data submission requirements as specified at § 512.720(a)(1)(i).

(iii) CMS does not assign a final score for the applicable ASM performance year to ASM participants who do all of the following:

(A) Meet the quality ASM performance category data submission requirements as specified at § 512.720(a)(1)(i).

(B)

(1) Do not receive a quality ASM performance category score under § 512.725(h)(4)(iii); or

(2) Do not receive a cost ASM performance category score under § 512.730(e)(3)(i).

(3) ***Complex patient scoring adjustment.*** CMS adds a complex patient scoring adjustment to the final score for the ASM performance year, if applicable, if an ASM participant meets the requirements to receive a final score greater than zero as described in paragraph (a)(2)(i) of this section and the criteria defined in paragraph (a)(3)(i) of this section for the applicable ASM performance year.

(i) The complex patient scoring adjustment is limited to ASM participants with a risk indicator at or above the risk indicator calculated median for their ASM cohort. To determine the median for the respective risk indicator (HCC and dual eligible proportion) for each ASM cohort, risk indicators associated to an ASM participant in the corresponding ASM cohort from the calendar year preceding the applicable ASM performance year, for all ASM participants within an ASM cohort who meet the data submission requirements for the quality ASM performance category at § 512.720(a)(1)(i) are used.

(ii) Beginning with the 2027 ASM performance year, for ASM participants, the complex patient scoring adjustment components are calculated as follows for the specific risk indicators:

(A) Medical complex patient scoring adjustment component = 1.5 + 4 * associated HCC standardized score calculated with the average HCC risk score assigned to beneficiaries (under the HCC risk adjustment model established by CMS in accordance with section 1853(a)(1) of the Act) seen by the ASM participant.

(B) Social complex patient scoring adjustment component = 1.5 + 4 * associated dual proportion standardized score.

(C) The components specified in paragraphs (a)(3)(ii)(A) and (B) of this section are added together to calculate one overall complex patient scoring adjustment. A standardized score for each risk indicator is determined based on the mean and standard deviation of the raw risk indicator score and provides a standardized measurement of how far each risk score is from the mean: (raw risk indicator score−risk indicator mean)/risk indicator standard deviation.

(iii) The complex patient scoring adjustment cannot exceed 10 and cannot be below zero.

(4) ***Small practice scoring adjustment*** —

(i) ***Scoring adjustment for an ASM participant that is in a small practice and is not a solo practitioner.*** CMS adds 10 points to the final score of an ASM participant that meets all of the following:

(A) Is in a small practice.

(B) Is not a solo practitioner.

(C) Meets the requirements to receive a final score greater than zero as described in paragraph (a)(2)(i) of this section for an applicable ASM performance year.

(ii) ***Scoring adjustment for ASM participant that is a solo practitioner.*** CMS adds 15 points to the final score of an ASM participant that is a solo practitioner and meets the requirements to receive a final score greater than zero as described in paragraph (a)(2)(i) of this section for an applicable ASM performance year.

(5) ***Final score formula.*** Final score = [quality ASM performance category score × quality ASM performance category weight) + (cost ASM performance category score × cost ASM performance category weight)] × 100 + improvement activities ASM performance category scoring adjustment + Promoting Interoperability ASM performance category scoring adjustment + complex patient scoring adjustment + small practice scoring adjustment. The final score cannot be below zero points or exceed 100 points.

(b) ***ASM performance report.*** For each ASM performance year, CMS provides each ASM participant with an ASM performance report, in a form and manner determined by CMS, containing all of the following:

(1) The ASM participant's score for each ASM performance category.

(2) The ASM participant's complex patient scoring adjustment under paragraph (a)(3) of this section, as applicable.

(3) The ASM participant's small practice or solo practitioner scoring adjustment under paragraph (a)(4) of this section, as applicable.

(4) The ASM participant's final score, as applicable.

(5) The ASM payment adjustment factor under § 512.750(c)(1).

(6) The ASM payment multiplier under § 512.750(c).

[90 FR 50022, Nov. 5, 2025; 91 FR 12081, Mar. 12, 2026]

PAYMENT AND TIMELY ERROR NOTICE PROCESS

§ 512.750 Payment adjustment.

(a) ***General.*** Except as described in paragraph (f) of this section, for covered professional services furnished by an ASM participant during an ASM payment year, CMS, in accordance with paragraph (d) of this section, multiplies the amount otherwise paid under Part B for the covered professional services by the ASM payment multiplier calculated for the ASM participant calculated under paragraph (c) of this section for the corresponding ASM performance year.

(b) ***Comparison of ASM participant performance.*** For the purpose of determining ASM payment adjustment factors and ASM payment multipliers applicable to adjustments to Part B payments for covered professional services in the corresponding ASM payment year, CMS separately compares final scores of ASM participants in each ASM cohort for the corresponding ASM performance year.

(c) ***ASM payment multiplier.*** Unless otherwise specified under paragraph (d) of this section, for each ASM participant within an ASM cohort for the applicable ASM payment year, CMS calculates an ASM payment multiplier as 1 plus the ASM payment adjustment factor determined under paragraph (c)(1) of this section.

(1) ***ASM payment adjustment factor.*** For each ASM participant with a final score greater than zero as described at § 512.745(a)(2)(i) within an ASM cohort for the applicable ASM performance year, CMS calculates an ASM payment adjustment factor using the formula: ASM payment adjustment factor = [(ASM risk level as described in paragraph (c)(1)(i) of this section) × (ASM participant's transformed final score as described in paragraph (c)(1)(ii) of this section) × (scaling factor applicable to the ASM incentive pool as described in paragraph (c)(1)(iv) of this section)]—ASM risk level as described in paragraph (c)(1)(i) of this section. For each ASM participant with a final score equal to zero as described at § 512.745(a)(2)(ii) within an ASM cohort for the applicable ASM payment year, CMS calculates an ASM payment adjustment factor equal to the negative of the applicable ASM level risk level as described in paragraph (c)(1)(i) of this section.

(i) ***ASM risk level.*** CMS sets an ASM risk level that is the magnitude of the maximum downside and upside risk to which an ASM participant is subject to during an ASM payment year.

(ii) ***Exchange function and transformed final score.*** CMS uses a logistic exchange function with a midpoint set at the median final score of the applicable ASM cohort from the applicable ASM performance year to transform each ASM's participant final score into a numerical value.

(iii) ***Incentive pool.*** CMS calculates an ASM incentive pool for each ASM cohort for an applicable ASM payment year using the formula: ASM incentive pool = (Sum of Medicare Part B payments for covered professional services paid to ASM participants with final scores in an ASM cohort during the applicable ASM performance year) × (ASM risk level as defined in paragraph (c)(1)(i) of this section) × (ASM redistribution percentage). The ASM redistribution percentage is set at 85 percent.

(iv) ***Scaling factor.*** CMS calculates a scaling factor for each ASM incentive pool for the applicable ASM payment year that ensures the estimated total payment adjustments would equal the ASM incentive pool. The scaling factor is calculated by dividing the total amount in the ASM incentive pool by the sum of all ASM participant's transformed final scores, multiplied by their respective total Medicare Part B covered professional services payments from the applicable ASM performance year and the applicable ASM risk level as specified under paragraph (c)(1)(i) of this section.

(2) [Reserved]

(d) ***No payment adjustments.*** CMS assigns an ASM payment adjustment factor of 0 and an ASM payment multiplier of 1 for the applicable ASM payment year that results in no payment adjustment to an ASM participant who does not receive a final score under § 512.745(a)(2)(iii) for the corresponding ASM performance year.

(e) ***Notification of ASM payment adjustments to ASM participants.*** CMS notifies each ASM participant of their ASM payment adjustment factor and corresponding ASM payment multiplier for the applicable ASM payment year in the ASM performance report under § 512.745(b) provided to each ASM participant for the applicable ASM performance year.

(f) ***Change in ASM participant TIN affiliation after ASM performance year and before the end of corresponding ASM payment year.***

(1) CMS adjusts payments to the different TIN using the ASM payment multiplier calculated for the ASM participant based on their performance in the corresponding ASM performance year for an NPI who meets all of the following:

(i) Is an ASM participant with a final score for an ASM performance year.

(ii) Submits Part B covered professional service claims during an ASM payment year using a different TIN than the TIN CMS identified them as an ASM participant for that ASM performance year and to which the ASM participant began assigning billing rights after the applicable ASM performance year but before the end of the corresponding ASM payment year.

(2) CMS adjusts claims using the highest ASM payment multiplier from all the TIN and NPI combinations that identified the NPI as an ASM participant for the corresponding ASM performance year for an NPI who meets all of the following:

(i) CMS identifies as an ASM participant under multiple TINs for a given ASM performance year.

(ii) Submits Part B covered professional service claims during an ASM payment year under a TIN by which CMS did not identify the ASM participant and to which the ASM participant began assigning billing rights after the applicable ASM performance year but before the end of the corresponding ASM payment year.

[90 FR 50022, Nov. 5, 2025; 91 FR 12082, Mar. 12, 2026]

§ 512.755 Timely error notice process.

(a) ***General.*** Subject to the limitations on review in § 512.170, an ASM participant may submit a written timely error notice for one or more calculations made and issued by CMS within the ASM performance report if the ASM participant believes an error occurred in calculations due to data quality, misapplication of methodology, or other issues.

(b) ***Requirements.*** If an ASM participant believes the ASM performance report contains a calculation error as described in paragraph (a) of this section, the ASM participant must submit a written timely error notice, in a form and manner specified by CMS, documenting the calculation error within 30 calendar days of issuance of the ASM performance report, unless specified by CMS.

(1) If the ASM participant does not provide written timely error notice in accordance with paragraph (a) of this section, then the ASM performance report is deemed final 30 calendar days after its issuance.

(2) Only an ASM participant may submit a written timely error notice described in this section.

(3) ***Sufficiency of information in written timely error notice.***

(i) CMS determines if the written timely error notice meets the requirements of this section and contains sufficient information to substantiate the request.

(ii) If the request is not compliant with the requirements of this section or requires additional information—

(A) CMS follows up with the ASM participant to request additional information in a form and manner as specified by CMS;

(B) The ASM participant must respond within 10 calendar days of CMS' request for additional information in a form and manner as specified by CMS; and

(C) If an ASM participant does not respond in accordance with paragraph (b)(3)(ii)(B) of this section, then the ASM performance report is deemed final.

(c) ***Process.***

(1) If CMS receives a written timely error notice within 30 calendar days of the issuance of the ASM performance report that CMS determines meets the requirements of paragraph (b) of this section, CMS issues an initial determination in writing within 30 calendar days of receipt to either confirm that there was an error in the calculation or verify that the calculation is correct.

(2) CMS reserves the right to extend the time for providing its initial final determination upon written notice to the ASM participant.

(d) ***Reconsideration request.*** An ASM participant who wishes to dispute an initial determination made in accordance with paragraph (c) of the section may invoke the reconsideration review process under § 512.190.

Data Sharing, Waivers, Safe Harbor, and Compliance

§ 512.760 Data sharing with ASM participants.

(a) ***General.*** CMS shares certain beneficiary-identifiable data as described in paragraphs (b), (c), and (e) of this section and certain aggregate data as described in paragraph (d) of this section with ASM participants regarding ASM beneficiaries and performance under the model.

(b) ***Beneficiary-identifiable data.*** CMS shares beneficiary-identifiable data with ASM participants as follows:

(1) CMS makes available certain beneficiary-identifiable data described in paragraph (b)(5) of this section for ASM participants to request for purposes of conducting 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 their patients who are ASM beneficiaries.

(2) An ASM participant that wishes to receive beneficiary-identifiable data for its ASM beneficiaries must do all of the following:

(i) Submit a formal request for the data, on at least an annual basis in a manner and form and by a date specified by CMS, which identifies the data being requested and attests that—

(A) The ASM participant is requesting this beneficiary-identifiable data as part of a covered entity, as defined at 45 CFR 160.103;

(B) The ASM participant's request reflects the minimum data necessary, as set forth in paragraph (c) of this section, for the ASM participant to conduct activities described in the first or second paragraph of the definition of health care operations at 45 CFR 164.501; and

(C) The ASM participant's use of beneficiary-identifiable data is limited to developing processes and engaging in appropriate activities related to coordinating care, improving the quality and efficiency of care, and conducting population-based activities relating to improving health or reducing health care costs that are applied uniformly to all ASM beneficiaries under the care of the ASM participant, and that these data are not to be used to reduce, limit or restrict care for specific Medicare beneficiaries.

(ii) To the extent practicable, limit the request to ASM beneficiaries whose claims were used to determine the requesting ASM participant's eligibility for ASM participation or to whom the requesting ASM participant provided care during an applicable ASM performance year.

(iii) Sign and submit a data sharing agreement with CMS as set forth in paragraph (e)(1) of this section.

(3) CMS shares beneficiary-identifiable data with an ASM participant on the condition that the ASM participant and other individuals or entities performing functions or services related to the ASM participant's activities, including but not limited to non-ASM participant parties in collaborative care arrangements with ASM participants, comply with all appliable laws addressing the appropriate use of data and the confidentiality and privacy of individually identifiable health information and the terms of the data sharing agreement described in paragraph (e)(1) of this section.

(4) CMS omits from the beneficiary-identifiable data any information that is subject to the regulations in 42 CFR part 2 governing the confidentiality of substance use disorder patient records.

(5) The beneficiary-identifiable data includes, when available, the following information:

(i) Unrefined (raw) Medicare Parts A, B, and D beneficiary-identifiable claims data used to determine ASM participant eligibility for an applicable ASM performance year; and

(ii) Unrefined (raw) Medicare Parts A, B, and D beneficiary-identifiable claims data for ASM beneficiaries who trigger an applicable EBCM episode with the ASM participant during the applicable ASM performance year.

(c) ***Minimum necessary data.*** The ASM participant must limit its request for beneficiary-identifiable data under paragraph (b) of this section to the minimum necessary to accomplish the permitted use of the data. The minimum necessary Medicare Parts A, B, and D data elements may include, but are not limited to the following:

(1) Medicare beneficiary identifier (ID).

(2) Procedure code.

(3) Sex.

(4) Diagnosis code.

(5) Claim ID.

(6) The from and through dates of service.

(7) The provider or supplier ID.

(8) The claim payment type.

(9) Date of birth and death, if applicable.

(10) Tax identification number.

(11) National provider identifier.

(d) ***Aggregated data feedback.*** CMS shares aggregated data on one or more select indicators of the ASM participant's performance, de-identified in accordance with 45 CFR 164.514(b), in a form and manner to be specified by CMS, when available, with ASM participants.

(e) ***ASM data sharing agreement.***

(1) To retrieve the beneficiary-identifiable data specified in paragraphs (b) and (c) of this section, the ASM participant must complete and submit, on at least an annual basis, a signed ASM data sharing agreement, to be provided in a form and manner and by a date specified by CMS, under which the ASM participant agrees, at a minimum to do all of the following:

(i) Comply with the requirements for use and disclosure of this beneficiary identifiable data that are imposed on covered entities by the HIPAA regulations, including but not limited to 45 CFR part 164, subparts A and E, and the requirements of ASM set forth in this part.

(ii) Comply with additional privacy, security, breach notification, and data retention requirements specified by CMS in the ASM data sharing agreement.

(iii) Contractually bind any and all downstream recipients of this beneficiary identifiable data, such as other individuals or entities performing functions or services related to the ASM participant's data sharing activities, including those that meet the definition of a business associate as defined at 45 CFR 160.103 and non-ASM participant parties to collaborative care arrangements described at § 512.771, to the same terms and conditions to which the ASM participant is itself bound in its data sharing agreement with CMS as a condition of the business associate's or non-ASM participant parties' receipt of the beneficiary-identifiable data obtained by the ASM participant.

(iv) That if the ASM participant or any downstream recipient misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the data sharing agreement, CMS may do any or all of the following:

(A) Deem the ASM participant ineligible to obtain the beneficiary-identifiable data under paragraph (b) of this section for any amount of time.

(B) Subject the ASM participant to additional sanctions and penalties available under applicable law.

(v) An ASM participant must comply with all applicable laws and the terms of the data sharing agreement to obtain beneficiary-identifiable data.

(2) CMS shares beneficiary-identifiable data with an ASM participant on the condition that the ASM participant and other individuals or entities performing functions or services related to the ASM participant's data sharing activities, including business associates as defined at 45 CFR 160.103 of the ASM participant and non-ASM participant parties to collaborative care arrangements described at § 512.771, comply with all relevant laws governing the use of data and the privacy and security of individually identifiable health information and the terms of the data sharing agreement described in paragraph (e)(1) of this section.

(f) ***Data custodian.*** An ASM participant must designate and provide the contact information for, in a form and manner identified by CMS, a data custodian who is responsible for ensuring compliance with privacy and security requirements, including all applicable laws and terms of the ASM data sharing agreement, and for notifying CMS of any incidents relating to unauthorized disclosures of beneficiary-identifiable data.

§ 512.765 Application of the CMS-sponsored model arrangements and patient incentives safe harbor.

(a) ***Application of the CMS-sponsored model arrangements safe harbor.*** CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (§ 1001.952(ii)(1)) is available to protect remuneration furnished in accordance with the collaborative care arrangements that meet all safe harbor requirements set forth in §§ 1001.952(ii) and 512.771.

(b) ***Application of the CMS-sponsored model patient incentives safe harbor.*** CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (§ 1001.952(ii)(2)) is available to protect remuneration furnished in ASM in the form of ASM beneficiary engagement incentives that meet all safe harbor requirements set forth in §§ 1001.952(ii) and 512.770.

§ 512.770 ASM beneficiary incentives.

(a) ***ASM beneficiary incentives.*** ASM participants may choose to provide in-kind patient engagement incentives, including but not limited to items of technology or services, to ASM beneficiaries, subject to the following conditions:

(1) ***Provision of incentive.***

(i) The incentive must be provided directly by the ASM participant or by an agent of the ASM participant under the ASM participant's direction and control to an ASM beneficiary who is an established patient of the ASM participant.

(ii) The ASM participant must be solely responsible for any costs associated with the provision of the incentive, including but not limited to, the retail value of the item or services offered as the ASM beneficiary incentive.

(2) The item or service provided must be reasonably connected to medical care provided by the ASM participant to an ASM beneficiary for an ASM targeted chronic condition.

(3) The item or service must be a preventive care item or service or an item or service that advances a clinical goal, as specified in paragraph (d) of this section, for an ASM beneficiary by engaging the ASM beneficiary in better managing an ASM targeted chronic condition.

(4) The item or service must not be tied to the receipt of items or services outside the services furnished by the ASM participant to the ASM beneficiary.

(5) The item or service must not be tied to the receipt of items or services from a particular provider or supplier.

(6) The availability of the items or services must not be advertised or promoted, except that an ASM beneficiary may be made aware of the availability of the items or services at the time the ASM beneficiary could reasonably benefit from them.

(7) The cost of the items or services must not be shifted to any Federal health care program, as defined at section 1128B(f) of the Act.

(8) The totality of items or services, including technology as described at paragraph (b) of this section, provided to an ASM beneficiary may not exceed $1,000 in retail value for any one ASM beneficiary.

(b) ***Technology provided to an ASM beneficiary.*** ASM beneficiary incentives involving technology are subject to the following additional conditions:

(1) Items or services involving technology provided to an ASM beneficiary must be the minimum necessary to advance a clinical goal, as listed in paragraph (d) of this section, for an ASM beneficiary.

(2) Items of technology exceeding $75 in retail value must—

(i) Remain the property of the ASM participant; and

(ii) Be retrieved from the ASM beneficiary—

(A) Upon the end of their care relationship with the ASM participant, with documentation of the ultimate date of retrieval. The ASM participant must document all retrieval attempts.

(*1*) In cases when the item of technology is not able to be retrieved, the ASM participant must determine why the item was not retrievable.

(*2*) If it was determined that the item was misappropriated, then the ASM participant must take steps to prevent future beneficiary incentives for that ASM beneficiary.

(*3*) Following this process, documented, diligent, good faith attempts to retrieve items of technology is deemed to meet the retrieval requirement; or

(B) If the provided technology breaks or is otherwise rendered unusable for its intended purposes, with documentation of the ultimate date of retrieval. The ASM participant may replace the unusable unit with the same or similar technology, to the extent practicable, that meets the requirements of paragraphs (a) and (b) of this section.

(c) ***Documentation of ASM beneficiary incentives.*** In addition to requirements at § 512.135 of this part ASM participants must do all of the following:

(1) Maintain documentation of items and services furnished as beneficiary incentives that exceed $75 in retail value.

(2) The documentation must be established contemporaneously with the provision of the items and services with a record established and maintained to include at least the following:

(i) The date the incentive is provided.

(ii) The identity of the ASM beneficiary to whom the item or service was provided.

(3) The documentation regarding items of technology exceeding $75 in retail value must also include contemporaneous documentation of any attempt to retrieve technology at the end of an episode, or why the items were not retrievable, as described in paragraph (b)(2)(ii) of this section.

(4) The ASM participant must retain and provide access to the required documentation.

(d) Clinical goals of *ASM.* The following are the clinical goals of ASM, which may be advanced through ASM beneficiary incentives:

(1) Promoting preventive care through improved management of ASM targeted chronic conditions.

(2) Empowering patients to actively participate and be accountable for quality and whole health outcomes.

(3) Facilitating meaningful and efficient coordination between specialists and primary care providers to increase independent physician participation in value-based payment programs.

§ 512.771 Collaborative care arrangements.

(a) ***General.*** Collaborative care arrangements must meet all of the following:

(1) Be in writing, signed by both parties, and contain the effective date of the arrangement.

(2) Be exclusively between the ASM participant and the primary care practice with whom the ASM participant shares at least one established patient who is an ASM beneficiary.

(3) The collaborative care arrangement must be entered into for the purpose of either of the following:

(i) Furthering the ASM participant's performance in the improvement activities ASM performance category at § 512.735.

(ii) Advancing the clinical goals of ASM as described in paragraph (b) of this section.

(4) Participation in a collaborative care arrangement must be voluntary and without penalty for nonparticipation.

(5) Both parties to the collaborative care arrangement must comply with all applicable statutes, regulations, and guidance, including without limitation the following:

(i) Federal criminal laws.

(ii) The False Claims Act (31 U.S.C. 3729 *et seq.*).

(iii) The anti-kickback statute (42 U.S.C. 1320a-7b(b)).

(iv) The civil monetary penalties law (42 U.S.C. 1320a-7a).

(v) The physician self-referral law (42 U.S.C. 1395nn).

(6) The opportunity to enter into a collaborative care arrangement, and the amount of any payment under a collaborative care arrangement, must not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business generated by, between, or among the parties to the collaborative care arrangement or any other person.

(7) Any payment between the parties set forth in a collaborative care arrangement must not exceed the sum total of the payment adjustments made to an ASM participant's claims for a given ASM performance year as a result of the application of the ASM payment adjustment factor to the ASM participant's Medicare Part B payments for covered professional services during an ASM payment year.

(8) Any payment or other remuneration set forth in the collaborative care arrangement must be solely between the parties to the arrangements. Any payment between the parties must be made by check, electronic funds transfer, or another traceable cash transaction.

(9) Both parties to the collaborative care arrangement must retain the ability to make decisions in the best interests of ASM beneficiaries, including the selection of clinicians, devices, supplies, and treatments.

(10) The collaborative care arrangement must not do either of the following:

(i) Induce any party to reduce or limit medically necessary services to any Medicare beneficiary.

(ii) Reward the provision of items and services that are medically unnecessary.

(11) ASM participants must maintain contemporaneous documentation, in accordance with § 512.135, regarding all collaborative care arrangements entered into, including the following:

(i) The relevant written agreements.

(ii) The date and amount of any payments between the parties.

(iii) A description of the methodology and accounting formula for determining the amount of any payments between the parties.

(12) The collaborative care arrangement must stipulate that any non-ASM participant party is considered a downstream recipient for CMS data sharing purposes, and must require the non-ASM participant party to comply with applicable data sharing requirements at § 512.760.

(13) Any non-ASM participant party to a collaborative care arrangement must be a downstream participant subject to the standard provisions for Innovation Center models specified in subpart A of this part 512.

(b) ***Clinical goals of ASM.*** The following are the clinical goals of ASM, which may be advanced through collaborative care arrangements:

(1) Promoting preventive care through improved management of ASM targeted chronic conditions.

(2) Empowering patients to actively participate and be accountable for quality and whole health outcomes.

(3) Facilitating meaningful and efficient coordination between specialists and primary care providers to increase independent physician participation in value-based payment programs.

(c) ***Collaborative care arrangement exclusions.*** An ASM participant may not enter into a collaborative care arrangement with a party that is excluded from participation in any Federal health care programs by the Inspector General.

§ 512.775 Medicare program waivers.

(a) ***Medicare payment waivers.*** Unless otherwise specified in § 512.710(a)(2), CMS waives the requirements of section 1848(q) of the Act, and its implementing regulations, for an ASM participant for each ASM performance year that the ASM participant meets the ASM eligibility criteria set forth in § 512.710(b).

(b) ***Waiver of certain telehealth requirements*** —

(1) ***Waiver of the geographic site requirements.*** Except for the geographic site requirements for a face-to-face encounter for home health certification, CMS waives the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act for ASM participants and ASM beneficiaries solely for services that—

(i) May be furnished via telehealth under existing Medicare program requirements; and

(ii) Are medically appropriate for treatment of an ASM targeted chronic condition.

(2) ***Waiver of the originating site requirements.*** Except for the originating site requirements for a face-to-face encounter for home health certification, CMS waives the originating site requirements under section 1834(m)(4)(C)(*ii*)(*I*) through (VIII) of the Act for episodes to permit a telehealth visit to originate in the beneficiary's home or place of residence solely for services that—

(i) May be furnished via telehealth under existing Medicare program requirements; and

(ii) Are medically appropriate for treatment of an ASM targeted chronic condition.

(3) ***Waiver of selected payment provisions.*** CMS waives payment requirements as follows:

(i) Under section 1834(m)(2)(B) of the Act so that the facility fee normally paid by Medicare to an originating site for a telehealth service is not paid if the service is originated in the beneficiary's home or place of residence.

(ii) Under section 1834(m)(2)(A) of the Act to allow the distant site payment for telehealth home visit HCPCS codes unique to ASM.

(4) ***Other requirements.*** All other requirements for Medicare coverage and payment of telehealth services continue to apply, including the list of specific services approved to be furnished by telehealth.

[90 FR 50022, Nov. 5, 2025; 91 FR 12082, Mar. 12, 2026]

§ 512.780 Extreme and uncontrollable circumstances.

(a) ***General rule.*** Except as specified in paragraph (b) of this section, CMS—

(1) Applies determinations made under the Quality Payment Program for whether an extreme and uncontrollable circumstance has occurred and the affected area during the ASM performance year; and

(2) Has sole discretion to determine the period during which an extreme and uncontrollable circumstance occurred.

(b) ***Additional criteria.***

(1) CMS has sole discretion to determine, based on information known to the agency prior to the beginning of the relevant ASM payment year, that data for an ASM participant are inaccurate, unusable, or otherwise compromised due to circumstances outside of the control of the clinician and its agents, including third-party intermediaries.

(2) CMS notifies ASM participants of the following:

(i) Its determination that the circumstances described at paragraph (b)(1) of this section exist; and

(ii) The impact of the circumstances described in paragraph (b)(1) of this section upon scoring methodology for affected ASM participants in a form and manner determined by CMS.

(c) ***Impact on final scores.***

(1) Except as described in paragraph (c)(2) of this section, an ASM participant who CMS identified as having been affected by a circumstance described in paragraphs (a) or (b) of this section is exempt from meeting data submission requirements identified at § 512.720 and does not receive a final score, resulting in a neutral payment adjustment for the corresponding ASM payment year.

(2) In the event that an ASM participant who CMS identified as having been affected by a circumstance described in paragraph (a) or (b) of this section submits data in accordance with the data submission requirements at § 512.720, CMS assigns the ASM participant a final score using the methodology described at § 512.745 for the applicable ASM performance year.