the model is not subject to administrative or judicial review.

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

Subpart A—General Provisions Related to Innovation Center Models

Subpart B—Radiation Oncology Model

Subpart C—ESRD Treatment Choices Model

Subpart D [Reserved]

Subpart E—Transforming Episode Accountability Model (TEAM)

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Subpart A—General Provisions Related to Innovation Center Models

§ 512.100 Basis and scope.

(a) *Basis.* This subpart implements certain general provisions for the Radiation Oncology Model implemented under subpart B (RO Model) and the End-Stage Renal Disease (ESRD) Treatment Choices Model implemented under subpart C (ETC Model), collectively referred to in this subpart as Innovation Center models. Except as specifically noted in this part, the regulations do not affect the applicability of other provisions affecting providers and suppliers under Medicare Fee-For-Service (FFS), including provisions regarding payment, coverage, or program integrity.

(b) *Scope.* The regulations in this subpart apply to model participants in the RO Model (except as otherwise noted in § 512.160(b)(6)) and to model participants in the ETC Model. This subpart sets forth the following:

(1) Basis and scope.

(2) Beneficiary protections.

(3) Model participant requirements for participation in model evaluation and monitoring, and record retention.

(4) Rights in data and intellectual property.

(5) Monitoring and compliance.

(6) Remedial action and termination by CMS.

(7) Limitations on review.

(8) Miscellaneous provisions on bankruptcy and notification.

§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.

Innovation Center model means the RO Model implemented under subpart B or the ETC Model implemented under subpart C.

Innovation Center model activities means any activities impacting the care of model beneficiaries related to the test of the Innovation Center model under the terms of this part.

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 under the terms of this part.

Model participant means an individual or entity that is identified as a participant in the Innovation Center model under the terms of this part.

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.

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.

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.

§ 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 noncompliant 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.

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]

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§ 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]

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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 either 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—

(i) At least 12 months after the beneficiary's latest transplant date; or

(ii) Less than 12 months after the beneficiary's latest transplant date and has a kidney transplant failure diagnosis code documented on any Medicare claim.

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]

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 June 30, 2027.

§ 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 June 30, 2026.

(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 June 30, 2027.

(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 – 1/1/2022 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
MY 8 – 7/1/2024 through 6/30/2025	PPA Period 8 – 1/1/2026 through 6/30/2026
MY 9 – 1/1/2025 through 12/31/2025	PPA Period 9 – 7/1/2026 through 12/31/2026
MY 10 – 7/1/2025 through 6/30/2026	PPA Period 10 – 1/1/2027 through 6/30/2027

§ 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 MY10, 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]

§ 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 MY1 and MY2, the numerator is the total number of home dialysis treatment beneficiary years plus one half the total number of self dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. For MY3 through MY10, 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 MY1 and MY2, the numerator is the total number of home dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY plus one half the total number of self dialysis treatment beneficiary years. For MY3 through MY10, 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 MY1 and MY2, 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. For MY3 through MY10, 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 MY1 and MY2, 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. For MY3 through MY10, 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 MY1 and MY2, 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. For MY3 through MY10, 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 MY1 and MY2, 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. For MY3 through MY10, 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 MY10, 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]

§ 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 MY10, are stratified as described in paragraph (b)(2) of this section. For MY5 through MY10, 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 ACHIEVMENT BENCHMARKS BY MEASUREMENT YEAR

MY1 and MY2	MY3 and MY4	MY5 and MY6	MY7 and MY8	MY9 and MY10	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).	1.4 * (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 Benchmark Year.	1.1 * (75th+ Percentile of benchmark rates for Comparison Geographic Areas during the. Benchmark Year)	1.2 * (75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.3 * (75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.4 * (75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.5
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).	1.4 * (50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1

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

MY1 and MY2	MY3 and MY4	MY5 and MY6	MY7 and MY8	MY9 and MY10	Points
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).	1.4 * (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).	1.4 * (<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	0

(2) *Stratifying achievement benchmarks.* For MY3 through MY10, 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 MY10, 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 MY10, 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 MY10, 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 ⅔ of the MPS and the ETC Participant's score for the transplant rate constitutes ⅓ 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 MY10, 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 ⅔ of the MPS and the ETC Participant's score for the transplant rate constitutes ⅓ of the MPS. CMS uses the following formula to calculate the ETC Participant's MPS for MY3 through MY10:

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]

§ 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

		Performance Payment Adjustment Period				
	MPS	1 and 2	3 and 4	5 and 6	7 and 8	9 and 10
Facility Performance Payment Adjustment	≤ 6	+4.0%	+5.0%	+6.0%	+7.0%	+8.0%
	≤ 5	+2.0%	+2.5%	+3.0%	+3.5%	+4.0%
	≤ 3.5	0%	0%	0%	0%	0%
	≤ 2	-2.5%	-3.0%	-3.5%	-4.5%	-5.0%
	≤ .5	-5.0%	-6.0%	-7.0%	-9.0%	-10.0%

Table 2 to § 512.380 – Clinician PPA Amounts and Schedule

		Performance Payment Adjustment Period				
	MPS	1 and 2	3 and 4	5 and 6	7 and 8	9 and 10
Clinician Performance Payment Adjustment	≤ 6	+4.0%	+5.0%	+6.0%	+7.0%	+8.0%
	≤ 5	+2.0%	+2.5%	+3.0%	+3.5%	+4.0%
	≤ 3.5	0%	0%	0%	0%	0%
	≤ 2	-2.5%	-3.0%	-3.5%	-4.0%	-4.5%
	≤ .5	-5.0%	-6.0%	-7.0%	-8.0%	-9.0%

§ 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.

(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]

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 [Reserved]

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) Decarbonization and resilience initiative.

§ 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).

ADI stands for Area Deprivation Index.

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.

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.

Decarbonization and Resilience Initiative means an initiative for TEAM participants that includes technical assistance on decarbonization and a voluntary reporting program where TEAM participants may annually report metrics and questions related to emissions in accordance with § 512.598.

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 national mean of the benchmark price for each MS–DRG/HCPCS episode type divided by the national mean of the risk-adjusted benchmark price for the same MS–DRG/HCPCS episode type.

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 equity goal means a targeted outcome relative to health equity plan performance measures.

Health equity plan means a document that identifies health equity goals, intervention strategies, and performance measures to improve health disparities identified within the TEAM participant's population of TEAM beneficiaries that the TEAM participant will aim to reduce as described in § 512.563.

Health equity plan intervention strategy means the initiative the TEAM participant creates and implements to reduce the identified health disparities as part of the health equity plan.

Health equity plan performance measure means a quantitative metric that the TEAM participant uses to measure changes in health disparities arising from the health equity plan intervention strategies.

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 in a given region, 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 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.

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 preliminary target price does not exceed the average of the total non-risk adjusted preliminary target 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.

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.

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 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).

Underserved community means a population sharing a particular characteristic, including geography, that has been systematically denied a full opportunity to participate in aspects of economic, social, and civic life.

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.

TEAM PARTICIPATION

§ 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).

(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.

§ 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 episode's date of the anchor procedure, as applicable.

(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, but

reconciles the episode based on the end date of the episode.

(b) *Preliminary target price calculation.* (1) 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) CMS uses the following baseline periods to determine baseline episode spending:

(i) Performance Year 1: Episodes beginning on January 1, 2022 through December 31, 2024.

(ii) Performance Year 2: Episodes beginning on January 1, 2023 through December 31, 2025.

(iii) Performance Year 3: Episodes beginning on January 1, 2024 through December 31, 2026.

(iv) Performance Year 4: Episodes beginning on January 1, 2025 through December 31, 2027.

(v) Performance Year 5: Episodes beginning on January 1, 2026 through December 31, 2028.

(3) 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) *Exception 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 § 512.540(a)(1)(ii).

(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, which is a multiplier that ensures that the average risk adjusted target price does not exceed the average unadjusted target 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 the following:

(i) The average regional episode spending for each MS–DRG/HCPCS episode type using the most recent calendar year of the applicable baseline period.

(ii) The difference between the average regional spending for each MS–DRG/HCPCS episode type during the most recent calendar year of the baseline period and the average regional spending for each MS–DRG/HCPCS episode type during the first years of the baseline period to determine the prospective trend factor.

(8) *Communication of preliminary target prices.* CMS communicates the preliminary target prices for each MS–DRG/HCPCS episode type for each region 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.

§ 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 social need 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 paragraph (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 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 social need 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 measures of social need:

(A) State ADI above the 8th decile.

(B) National ADI 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 measures of social need in § 512.545(a)(1)(iii)(A).

(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, as of the first day of the episode, of each of the following conditions:

(i) CABG episode category.

(A) Prior post-acute care use.

(B) HCC 18: Diabetes with Chronic Complications.

(C) HCC 46: Severe Hematological Disorders.

(D) HCC 58: Major Depressive, Bipolar, and Paranoid Disorders.

(E) HCC 84: Cardio-Respiratory Failure and Shock.

(F) HCC 85: Congestive Heart Failure.

(G) HCC 86: Acute Myocardial Infarction.

(H) HCC 96: Specified Heart Arrhythmias.

(I) HCC 103: Hemiplegia/Hemiparesis.

(J) HCC 111: Chronic Obstructive Pulmonary Disease.

(K) HCC 112: Fibrosis of Lung and Other Chronic Lung Disorders.

(L) HCC 134: Dialysis Status.

(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) Dementia without complications.

(D) Prior post-acute care use.

(E) HCC 8: Metastatic Cancer and Acute Leukemia.

(F) HCC 18: Diabetes with Chronic Complications.

(G) HCC 22: Morbid Obesity.

(H) HCC 58: Major Depressive, Bipolar, and Paranoid Disorders.
(I) HCC 78: Parkinson's and Huntington's Diseases.
(J) HCC 85: Congestive Heart Failure.
(K) HCC 86: Acute Myocardial Infarction.
(L) HCC 103: Hemiplegia/Hemiparesis.
(M) HCC 111: Chronic Obstructive Pulmonary Disease.
(N) HCC 112: Fibrosis of Lung and Other Chronic Lung Disorders.
(O) HCC 134: Dialysis Status.
(P) HCC 170: Hip Fracture/Dislocation.
(iii) Major Bowel Procedure episode category.
(A) Long-term institutional care use.
(B) HCC 11: Colorectal, Bladder, and Other Cancers.
(C) HCC 18: Diabetes with Chronic Complications.
(D) HCC 21: Protein-Calorie Malnutrition.
(E) HCC 33: Intestinal Obstruction/Perforation.
(F) HCC 82: Respirator Dependence/Tracheostomy Status.
(G) HCC 85: Congestive Heart Failure.
(H) HCC 86: Acute Myocardial Infarction.
(I) HCC 103: Hemiplegia/Hemiparesis.
(J) HCC 111: Chronic Obstructive Pulmonary Disease.
(K) HCC 112: Fibrosis of Lung and Other Chronic Lung Disorders.
(L) HCC 134: Dialysis Status.
(M) HCC 188: Artificial Openings for Feeding or Elimination.
(iv) SHFFT episode category.
(A) HCC 18: Diabetes with Chronic Complications.
(B) HCC 22: Morbid Obesity.
(C) HCC 82: Respirator Dependence/Tracheostomy Status.
(D) HCC 83: Respiratory Arrest.
(E) HCC 84: Cardio-Respiratory Failure and Shock.
(F) HCC 85: Congestive Heart Failure.
(G) HCC 86: Acute Myocardial Infarction.
(H) HCC 96: Specified Heart Arrhythmias.
(I) HCC 103: Hemiplegia/Hemiparesis.
(J) HCC 111: Chronic Obstructive Pulmonary Disease.
(K) HCC 112: Fibrosis of Lung and Other Chronic Lung Disorders.
(L) HCC 134: Dialysis Status.
(M) HCC 157: Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone.
(N) HCC 158: Pressure Ulcer of Skin with Full Thickness Skin Loss.
(O) HCC 161: Chronic Ulcer of Skin, Except Pressure.
(P) HCC 170: Hip Fracture/Dislocation.
(v) Spinal Fusion episode category.
(A) Prior post-acute care use.
(B) HCC 8: Metastatic Cancer and Acute Leukemia.
(C) HCC 18: Diabetes with Chronic Complications.
(D) HCC 22: Morbid Obesity.
(E) HCC 40: Rheumatoid Arthritis and Inflammatory Connective Tissue Disease.
(F) HCC 58: Major Depressive, Bipolar, and Paranoid Disorders.
(G) HCC 85: Congestive Heart Failure.
(H) HCC 86: Acute Myocardial Infarction.
(I) HCC 96: Specified Heart Arrhythmias.
(J) HCC 103: Hemiplegia/Hemiparesis.
(K) HCC 111: Chronic Obstructive Pulmonary Disease.
(L) HCC 112: Fibrosis of Lung and Other Chronic Lung Disorders.
(M) HCC 134: Dialysis Status.

(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 national mean of the benchmark price for each MS–DRG/HCPCS episode type divided by the national mean of the risk-adjusted benchmark price for the same MS–DRG/HCPCS episode type.

(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) *Retrospective trend factor*. CMS calculates 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).

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 and the Hospital-Acquired Condition Reduction 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 years 2 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; 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.

(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):

(*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 does not assign a scaled quality measure score if the TEAM participant has no raw quality measure score.

(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.

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)) 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.

(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.

(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)).

(5) CMS subtracts the performance year spending amount determined under paragraph (c)(1–2) of this section from the aggregated reconciliation target price amount determined under paragraph (c)(4) of this section to determine the reconciliation amount.

(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.

§ 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) Gender.

(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.

§ 512.563 Health equity reporting.

(a) *Health equity plans.* (1) The TEAM participant may voluntarily submit a health equity plan to CMS for each performance year that includes the elements specified in paragraph (a)(2) of this section, in a form and manner and by the date specified by CMS.

(2) Health equity plans must include the following elements:

(i) Identifies health disparities in the TEAM participant's population of TEAM beneficiaries.

(ii) Identifies health equity goals and describes how the TEAM participant uses the health equity goals to monitor and evaluate progress in reducing the identified health disparities.

(iii) Describes the health equity plan intervention strategy.

(iv) Identifies health equity plan performance measure(s), the data sources used to construct the performance measures, and an approach to monitor and evaluate the measures.

(b) *Health-related social needs screening and reporting.* (1) For all performance years, the TEAM participant may voluntarily submit aggregated health-related social needs screening and screened-positive data in a form and manner and by the dates specified by CMS. The health-related social needs screening and reporting must include the elements specified in paragraph (a)(2) of this section.

(2) CMS uses the following measures from the Hospital Inpatient Quality Reporting Program for the TEAM participants who opt to voluntarily submit aggregated health-related social needs screening and screened-positive data.

(i) Screening for Social Drivers of Health (SDOH–1; CMIT ID #1664).

(ii) Screen Positive Rate for Social Drivers of Health (SDOH–2; CMIT ID #1662).

(3) For all performance years, TEAM participants that voluntarily submit data health-related social needs screening and screened-positive data as specified in paragraphs (b)(1) and (2) of this section may voluntarily submit information on referral policies and procedures for beneficiaries that screen positive for health-related social needs in a form and manner and by dates specified by CMS.

(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.

§ 512.564 Referral to primary care services.

(a) A 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.

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.

MEDICARE PROGRAM WAIVERS

§ 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. Qualified SNFs are rated an overall of 3 stars or better for at least 7 of the 12 months.

(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.

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.

§512.598 Decarbonization and resilience initiative.

(a) *Voluntary reporting.* A TEAM participant may elect to respond to questions and report metrics related to the TEAM participant's, or the TEAM participant's corporate affiliate's, emissions to CMS on an annual basis following each performance period. Voluntary reporting includes the following metrics:

(1) Organizational questions, which are a set of questions about the TEAM participants' sustainability team and sustainability activities.

(2) Building energy metrics, which are a set of metrics related to measuring and reporting GHG emissions related to energy use at TEAM participant facilities.

(i) Building energy metrics are based on the ENERGY STAR® Portfolio Manager® guidelines for the time of submission. TEAM participants reporting these metrics must submit using ENERGY STAR Portfolio Manager in the manner described in paragraph (b) of this section.

(ii) Metrics to be collected include all of the following:

(A) ENERGY STAR® Score for Hospitals as defined in the ENERGY STAR® Portfolio Manager® as well as supporting data which may include energy use intensity, electricity, natural gas, and other source emissions and normalizing factors such as building size, number of full-time equivalent workers, number of staffed beds, number of magnetic resonance imaging machines, zip codes, and heating and cooling days, as specified in the ENERGY STAR® Portfolio Manager®.

(B) Energy cost, to capture total energy costs, as specified in the ENERGY STAR® Portfolio Manager®.

(C) Total, direct, and indirect GHG emissions and emissions intensity as specified in the ENERGY STAR® Portfolio Manager®.

(3) Anesthetic gas metrics, which are a set of metrics related to measuring and managing emissions from anesthetic gas which include all of the following:

(i) Total greenhouse gas emissions from inhaled anesthetics based on purchase records.

(ii) Normalization factors that may include information on anesthetic hours, operating rooms, or MAC-hour equivalents.

(iii) Assessment questions based on key actions recommended for reducing emissions for anesthetic gases.

(4) Transportation metrics, which are a set metrics that focus on greenhouse gases related to leased or owned vehicles and may include any of the following:

(i) Gallons for owned and leased vehicles.

(ii) Normalization factors that may include patient encounter volume and the number of full-time equivalent (FTE) employees.

(iii) Assessment questions on key actions to reduce transportation emissions.

(b) *Manner and timing of reporting.* (1) If the TEAM participant elects to report the metrics in paragraph (b) of this section to CMS, such information must be reported to CMS in a form and manner specified by CMS for each performance year, including the use of ENERGY STAR® Portfolio Manager® for the building energy metrics at paragraph (a)(2) of this section and a survey and questionnaire for questions and metrics at paragraphs (a)(1), (3), and (4) of this section.

(2) If the TEAM participant chooses to participate, the TEAM participant must report the information to CMS—

(i) No later than 120 days in the year following the performance year; or

(ii) A later date as specified by CMS.

(c) *Individualized feedback reports; recognition.* If a TEAM participant elects to report all the metrics specified in paragraph (a) of this section to CMS, in the manner specified in paragraph (b) of this section, CMS annually provides the TEAM participant with the following:

(1) Individualized feedback reports, which may summarize facilities' emissions metrics and may include benchmarks, as feasible, for normalized metrics to compare facilities, in aggregate, to other TEAM participants in the Decarbonization and Resilience Initiative. A TEAM participant that receives individualized feedback reports from CMS must request approval from CMS in writing and receive written approval from CMS prior to publication or public disclosure of data or information contained in the individualized feedback reports.

(2) Publicly reported hospital recognition for the TEAM participant's commitment to decarbonization through a hospital recognition badge publicly reported on a CMS website, which may include recognition of the TEAM participant's corporate affiliates when such data has been submitted as specified in paragraph (a) of this section.