maintain existing outreach programs. The plan must—

(1) Address cancer prevention for cancers that are prevalent in the designated populations or cancers that are targeted by the qualifying hospital, interventions, and goals for decreasing the targeted cancer rates during the loan deferment program; and

(2) Address early diagnosis of cancers that are prevalent in the designated populations or cancers that are targeted by the qualifying hospital, interventions, and goals for improving early diagnosis rates for the targeted cancer(s) during the loan deferment period;

(3) Address cancer treatment for cancers that are prevalent in the designated populations or cancers that are targeted by the qualifying hospital, interventions, and goals for improving cancer treatment rates for the targeted cancer(s) during the loan deferment; and

(4) Identify the measures that will be used to determine the qualifying hospital's annual progress in meeting the initial goals specified in paragraphs (a)(1) through (a)(3) of this section.

(b) *Unique research resources.* The plan must specify how the qualifying hospital will establish or maintain existing unique research resources or an affiliation with an entity that has unique research resources.

§ 505.17 Reporting requirements for meeting the conditions for loan forgiveness.

(a) *Annual reporting requirements.* On an annual basis, beginning one year from the date that CMS notified the qualifying hospital of the loan award, the qualifying hospital must submit a report to CMS that updates the plan specified in § 505.15 by—

(1) Describing the qualifying hospital's progress in meeting its initial plan goals;

(2) Describing any changes to the qualifying hospital's initial plan goals; and

(3) Including at least one measure used to track the qualifying hospital's progress in meeting its plan goals.

(b) *Review of annual reports.* CMS will review each qualifying hospital's annual report to provide the hospital with feedback regarding its loan forgiveness status. If CMS determines that the annual report shows that the qualifying hospital has fulfilled the conditions, plan criteria, and reporting requirements for loan forgiveness specified in §§ 505.13, 505.15, and 505.17, CMS will notify the qualifying hospital in writing that the loan is forgiven.

(c) *Final annual reporting requirements.* A qualifying hospital must submit its final report to CMS at least 6 months before the end of the loan deferment period specified in § 505.7(b).

§ 505.19 Approval or denial of loan forgiveness.

(a) *Approval of loan forgiveness.* If CMS determines that a qualifying hospital has met the conditions, plan criteria, and reporting requirements for loan forgiveness specified in §§ 505.13, 505.15, and 505.17, CMS will send a written notification of approval for loan forgiveness to the qualifying hospital by the earlier of—

(1) 30 days from the date of receipt of the annual report that shows the qualifying hospital has satisfied the requirements for loan forgiveness; or

(2) 90 days before the end of the loan deferment period defined in § 505.7(b).

(b) *Denial of loan forgiveness.* If CMS determines that a qualifying hospital has not met the conditions, plan criteria, or reporting requirements for loan forgiveness specified in § 505.13, § 505.15, or § 505.17 of this part, CMS will send a written notification of denial of loan forgiveness to the qualifying hospital at least 30 days before the end of the loan deferment period defined in § 505.7(b).

PART 510—COMPREHENSIVE CARE FOR JOINT REPLACEMENT MODEL

Subpart A—General Provisions

Sec.

Subpart B—Comprehensive Care for Joint Replacement Program Participants

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

SOURCE: 80 FR 73540, Nov. 24, 2015, unless otherwise noted.

Subpart A—General Provisions

§510.1 Basis and scope.

(a) *Basis.* This part implements the test of the Comprehensive Care for Joint Replacement model under section 1115A of the Act. Except as specifically noted in this part, the regulations under this part must not be construed to affect the payment, coverage, program integrity, or other requirements (such as those in parts 412 and 482 of this chapter) that apply to providers and suppliers under this chapter.

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

(1) The participants in the Comprehensive Care for Joint Replacement model.

(2) The episodes being tested in the model.

(3) The methodology for pricing and payment under the model.

(4) Quality performance standards and quality reporting requirements.

(5) Safeguards to ensure preservation of beneficiary choice and beneficiary notification.

§510.2 Definitions.

For the purposes of this part, the following definitions are applicable unless otherwise stated:

ACO means an accountable care organization, as defined at §425.20 of this chapter, that participates in the Shared Savings Program and is not in Track 3.

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.

Actual episode payment means the sum of standardized Medicare claims payments for the items and services that are included in the episode in accordance with §510.200(b), excluding the items and services described in §510.200(d).

Age bracket risk adjustment factor means the coefficient of risk associated with a patient's age bracket, calculated as described in §510.301(a)(1).

Alignment payment means a payment from a CJR collaborator to a participant hospital under a sharing arrangement, for the sole purpose of sharing the participant hospital's responsibility for making repayments to Medicare.

Anchor hospitalization means the initial hospital stay upon admission for a lower extremity joint replacement, for which the institutional claim is billed through the IPPS. Anchor hospitalization also includes an inpatient hospital admission within 3 days after an outpatient Total Knee Arthroplasty (TKA) or Total Hip Arthroplasty (THA).

Anchor procedure means a TKA or THA procedure that is permitted and paid for by Medicare when performed in a hospital outpatient department (HOPD) and billed through the OPPS, except when the beneficiary is admitted to an inpatient hospital stay within 3 days after the TKA or THA.

Applicable discount factor means the discount percentage established by the participant hospital's quality category as determined in § 510.315 and that is applied to the episode benchmark price for purposes of determining a participant hospital's Medicare repayment in performance years 2 and 3.

Area means, as defined in § 400.200 of this chapter, the geographical area within the boundaries of a State, or a State or other jurisdiction, designated as constituting an area with respect to which a Professional Standards Review Organization or a Utilization and Quality Control Peer Review Organization has been or may be designated.

BPCI stands for the Bundled Payment for Care Improvement initiative.

BPCI Advanced stands for the Bundled Payments for Care Improvement Advanced Model.

CCN stands for CMS certification number.

CEC stands for Comprehensive ESRD Care Initiative.

CEHRT means certified electronic health record technology that meets the requirements of 45 CFR 170.102. .

CJR beneficiary means a beneficiary who meets the beneficiary inclusion criteria in § 510.205 and who is in a CJR episode.

CJR 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) Physician Group Practice (PGP).
(11) Hospital.
(12) CAH.
(13) Non-Physician Provider Group Practice (NPPGP).
(14) Therapy Group Practice (TGP).

CJR–HCC condition count risk adjustment factor means the coefficient of risk associated with a patient's total number of CMS Hierarchical Condition Categories, calculated as described in § 510.301(a)(1).

CJR reconciliation report means the report prepared after each reconciliation that CMS provides to each participant hospital notifying the participant hospital of the outcome of the reconciliation.

Collaboration agent means an individual or entity that is not a CJR 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 CJR 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 CJR collaborator.

Composite quality score means a score computed for each participant hospital to summarize the hospital's level of quality performance and improvement on specified quality measures as described in § 510.315.

Core-based statistical area (CBSA) means a statistical geographic entity 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.

COVID–19 Diagnosis Code means any of the following ICD–10–CM diagnosis codes:

(1) B97.29;

(2) U07.1; or

(3) Any other ICD–10–CM diagnosis code that is recommended by the Centers for Disease Control and Prevention for the coding of a confirmed case of COVID–19.

Critical access hospital (CAH) means a hospital designated under subpart F of part 485 of this chapter.

Distribution arrangement means a financial arrangement between a CJR 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 CJR 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 CJR collaborator or a collaboration agent and who is a PGP member, an NPPGP member, or a TGP member 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 distributing some or all of a distribution payment received by the PGP, NPPGP, or TGP.

Downstream distribution payment means a payment from a collaboration agent that is both a PGP, NPPGP, or TGP and an ACO participant to a downstream collaboration agent, under a downstream distribution arrangement, composed only of distribution payments.

Dual-eligibility risk adjustment factor means the coefficient of risk associated with beneficiaries that are eligible for full Medicaid benefits or beneficiaries that are not eligible for full Medicaid benefits, calculated as described in §510.301(a)(1).

EFT stands for electronic funds transfer.

Episode benchmark price means a dollar amount assigned to CJR episodes based on historical episode payment data (3 years of historical Medicare payment data grouped into CJR episodes according to the episode definition as described in §510.200(b)) prior to the application of the effective discount factor or applicable discount factor, as described in §510.300(c).

Episode of care (or Episode) means all Medicare Part A and B items and services described in §510.200(b) (and excluding the items and services described in §510.200(d)) that are furnished to a beneficiary described in §510.205 during the time period that begins with the beneficiary's admission to an anchor hospitalization or, on or after July 4, 2021, the date of admission to an anchor hospitalization or the date of the anchor procedure, as applicable, and ends on the 90th day after the following, as applicable:

(1) The date of discharge from the anchor hospitalization (with the day of discharge itself being counted as the first day of the 90-day post-discharge period); or

(2) The date of service for the anchor procedure.

ESRD stands for end stage renal disease.

Gainsharing payment means a payment from a participant hospital to a CJR collaborator, under a sharing arrangement, composed of only reconciliation payments or internal cost savings or both.

HCAHPS stands for Hospital Consumer Assessment of Healthcare Providers and Systems.

HCPCS stands for Healthcare Common Procedure Coding System.

HHA means a Medicare-enrolled home health agency.

Historical episode payment means the expenditures for historical episodes that occurred during the historical period used to determine the episode benchmark price.

Hospital means a provider subject to the prospective payment system specified in § 412.1(a)(1) of this chapter.

ICD–CM stands for International Classification of Diseases, Clinical Modification.

Inpatient prospective payment systems (IPPS) means the payment systems for subsection (d) hospitals as defined in section 1886(d)(1)(B) of the Act.

Internal cost savings means the measurable, actual, and verifiable cost savings realized by the participant hospital resulting from care redesign undertaken by the participant hospital in connection with providing items and services to beneficiaries within specific CJR episodes of care. Internal cost savings does not include savings realized by any individual or entity that is not the participant hospital.

IPF stands for inpatient psychiatric facility.

IRF stands for inpatient rehabilitation facility.

Low-volume hospital means a hospital identified by CMS as having fewer than 20 LEJR episodes in total across the 3 historical years of data used to calculate the performance year 1 CJR episode target prices.

Lower-extremity joint replacement (LEJR) means any procedure that is within MS–DRG 469 or 470, or, on or after October 1, 2020, MS–DRG 521 or 522, including lower-extremity joint replacement procedures or reattachment of a lower extremity.

LTCH stands for long-term care hospital.

Mandatory MSA means an MSA designated by CMS as a mandatory participation MSA in accordance with § 510.105(a).

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.

Metropolitan Statistical Area (MSA) means a core-based statistical area associated with at least one urbanized area that has a population of at least 50,000.

Net payment reconciliation amount (NPRA) means the amount determined in accordance with § 510.305(e) or (m).

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

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

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

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

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

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

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

NPI stands for National Provider Identifier.

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

OIG stands for the Department of Health and Human Services Office of the Inspector General.

OP THA/OP TKA means a total hip arthroplasty or total knee

arthroplasty, respectively, 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.

Participant hospital means one of the following:

(1) During performance years 1 and 2 of the CJR model and the period from January 1, 2018 to January 31, 2018 of performance year 3, a hospital (other than a hospital excepted under §510.100(b)) with a CCN primary address located in one of the geographic areas selected for participation in the CJR model in accordance with §510.105.

(2) Between February 1, 2018 and September 30, 2021 a hospital (other than a hospital excepted under §510.100(b)) that is one of the following:

(i) A hospital with a CCN primary address located in a mandatory MSA as of February 1, 2018 that is not a rural hospital or a low-volume hospital on that date.

(ii) A hospital that is a rural hospital or low-volume hospital with a CCN primary address located in a mandatory MSA that makes an election to participate in the CJR model in accordance with §510.115.

(iii) A hospital with a CCN primary address located in a voluntary MSA that makes an election to participate in the CJR model in accordance with §510.115.

(3) Beginning October 1, 2021, a hospital that is not a rural hospital or a low-volume hospital as defined in §510.2, as of July 4, 2021 (based on the date of the CMS notification letter and not the effective date of the rural reclassification, if applicable) with a CCN primary address located in a mandatory MSA.

PBPM stands for per-beneficiary-per-month.

Performance year means one of the years in which the CJR model is being tested. Performance years for the model correlate to calendar years with the exceptions of performance year 1, which is April 1, 2016 through December 31, 2016, performance year 5, which is January 1, 2020 through September 30, 2021, and performance year 6 which is October 1, 2021 through December 31, 2022. For reconciliation purposes, performance year 5 is divided into two subsets, performance year subset 5.1 (January 1, 2020 through December 31, 2020) and performance year subset 5.2 (January 1, 2021 through September 30, 2021).

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 Medicare Parts A and B payments for items and services that are furnished to a beneficiary within 30 days after the end of the beneficiary's episode.

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

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

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

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

Quality-adjusted target price means the dollar amount assigned to CJR episodes as the result of adjusting the episode benchmark price by the participant hospital's effective discount factor or applicable discount factor based on the participant hospital's quality category, as described in §§510.300(c) and 510.315(f).

Quality improvement points are points that CMS adds to a participant hospital's composite quality score for a measure if the hospital's performance percentile on an individual quality measure for performance years 2 through 4 and 6 through 8, or for performance year subsets of performance year 5, increases from the previous performance year or performance year subset by at least 2 deciles on the performance percentile scale, as described in §510.315(d). For performance year 1, CMS adds quality improvement points to a participant hospital's composite quality score for a measure if the hospital's performance percentile on an individual quality measure increases from the corresponding time period in the previous year by at least 2 deciles

on the performance percentile scale, as described in § 510.315(d).

Quality performance points are points that CMS adds to a participant hospital's composite quality score for a measure based on the performance percentile scale and for successful data submission of patient-reported outcomes.

Reconciliation payment means a payment made by CMS to a CJR participant hospital as determined in accordance with § 510.305(f) or (l).

Reconciliation target price means, for performance years 6 through 8, the target price applied to an episode at reconciliation, as determined in accordance with § 510.301.

Region means one of the nine U.S. census divisions, as defined by the U.S. Census Bureau.

Repayment amount means the amount owed by a participant hospital to CMS, as reflected on a reconciliation report.

Rural hospital means an IPPS hospital that meets one of the following definitions:

(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.

(3) Has reclassified as a rural hospital under § 412.103 of this chapter.

Rural referral center (RRC) has the same meaning given this term under § 412.96 of this chapter.

Sharing arrangement means a financial arrangement between a participant hospital and a CJR collaborator for the sole purpose of making gainsharing payments or alignment payments under the CJR model.

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.

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

Therapist means one of the following individuals as defined at § 484.4 of this chapter:

(1) Physical therapist.

(2) Occupational therapist.

(3) Speech-language pathologist.

Therapist in private practice means a therapist that—

(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/THA stands for total knee arthroplasty/total hip arthroplasty.

Voluntary MSA means an MSA designated by CMS as a voluntary participation MSA in accordance with § 510.105(a).

[80 FR 73540, Nov. 24, 2015, as amended at 82 FR 610, 611, Jan. 3, 2017; 82 FR 57103, Dec. 1, 2017; 85 FR 19292, Apr. 6, 2020; 85 FR 71198, Nov. 6, 2020; 86 FR 23569, May 3, 2021]

Subpart B—Comprehensive Care for Joint Replacement Program Participants

§ 510.100 Episodes being tested.

(a) *Initiation of an episode.* An episode is initiated when, with respect to a beneficiary described in § 510.205—

(1) The participant hospital admits the beneficiary for an anchor hospitalization; or

(2) On or after July 4, 2021, an anchor procedure is performed at the participant hospital.

(b) *Exclusions.* A hospital is excluded from being a participant hospital, but only so long as any of the following conditions apply:

(1) The hospital is an episode initiator for an LEJR episode in the risk-bearing period of Models 2 or 4 of BPCI.

(2) The hospital is participating in Model 1 of BPCI.

(3) These exclusions cease to apply as of the date that the hospital no longer

meets any of the conditions specified in this paragraph.

[80 FR 73540, Nov. 24, 2015, as amended at 86 FR 23570, May 3, 2021]

§ 510.105 Geographic areas.

(a) *General.* The geographic areas for inclusion in the CJR model are obtained based on a stratified random sampling of certain MSAs in the United States.

(1) All counties within each of the selected MSAs are selected for inclusion in the CJR model.

(2) Beginning with performance year 3, the selected MSAs are designated as either mandatory participation MSAs or voluntary participation MSAs.

(3) Beginning with performance year 6, only the 34 MSAs designated as mandatory participation MSAs as of performance year 3.

(b) *Stratification criteria.* Geographic areas in the United States are stratified according to the characteristics that CMS determines are necessary to ensure that the model is tested on a broad range of different types of hospitals that may face different obstacles and incentives for improving quality and controlling costs.

(c) *Exclusions.* CMS excludes from the selection of geographic areas MSAs that met the following criteria:

(1) Had fewer than 400 episodes between July 1, 2013 and June 30, 2014.

(2) Had fewer than 400 non-Model 1, 2, or 4 BPCI episodes as of October 1, 2015.

(3) Failed either or both of the following rules regarding participation in BPCI:

(i) More than 50 percent of eligible episodes initiated in a BPCI Model 2 or 4 initiating hospital.

(ii) More than 50 percent of eligible episodes that included SNF or HHA services, where the SNF or HHA services were furnished by a BPCI Model 3 initiating HHA or SNF.

(4) For MSAs including both Maryland and non-Maryland counties, more than 50 percent of eligible episodes were initiated at a Maryland hospital.

[80 FR 73540, Nov. 24, 2015, as amended at 82 FR 57103, Dec. 1, 2017; 86 FR 23570, May 3, 2021]

§ 510.110 Access to records and retention.

Participant hospitals, CJR collaborators, collaboration agents, downstream collaboration agents, and any other individuals or entities performing CJR activities must do all of the following:

(a) Allow the Government, including CMS, OIG, HHS and the Comptroller General or their designees, scheduled and unscheduled access to all books, contracts, records, documents and other evidence (including data related to utilization and payments, quality criteria, billings, lists of CJR collaborators, sharing arrangements, distribution arrangements, downstream distribution arrangements and the documentation required under §§ 510.500(d) and 510.525(c)) sufficient to enable the audit, evaluation, inspection or investigation of any of the following:

(1) The individual's or entity's compliance with CJR model requirements.

(2) The calculation, distribution, receipt, or recoupment of gainsharing payments, alignment payments, distribution payments, and downstream distribution payments.

(3) The obligation to repay any reconciliation payments owed to CMS.

(4) The quality of the services furnished to a CJR beneficiary during a CJR episode.

(5) The sufficiency of CJR beneficiary notifications.

(6) The accuracy of the CJR participant hospital's submissions under CEHRT use requirements.

(b) Maintain all such books, contracts, records, documents, and other evidence for a period of 10 years from the last day of the participant hospital's participation in the CJR model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

(1) CMS determines a particular record or group of records should be retained for a longer period and notifies the participant hospital at least 30 calendar days before the disposition date; or

(2) There has been a dispute or allegation of fraud or similar fault against the participant hospital, CJR collaborator, collaboration agents, downstream collaboration agent, or any

other individual or entity performing CJR activities in which case the records must be maintained for 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault.

[82 FR 612, Jan. 3, 2017]

§ 510.115 Voluntary participation election.

(a) *General.* To continue participation in performance year 3 and participate in performance year 4 and performance year 5, the following hospitals must submit a written participation election letter as described in paragraph (c) of this section during the voluntary participation election period specified in paragraph (b) of this section:

(1) Hospitals (other than those excluded under § 510.100(b)) with a CCN primary address in a voluntary MSA.

(2) Low-volume hospitals with a CCN primary address in a mandatory MSA.

(3) Rural hospitals with a CCN primary address in a mandatory MSA.

(b) *Voluntary participation election period.* The voluntary participation election period begins on January 1, 2018 and ends on January 31, 2018.

(c) *Voluntary participation election letter.* The voluntary participation election letter serves as the model participation agreement. CMS accepts the voluntary participation election letter if the letter meets all of the following criteria:

(1) Includes the following:

(i) Hospital name.

(ii) Hospital address.

(iii) Hospital CCN.

(iv) Hospital contact name, telephone number, and email address.

(v) Model name (that is, CJR model).

(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 the CJR model; 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 quality data or other information that CMS uses in its reconciliation processes.

(3) Is signed by the hospital administrator, CFO or CEO.

(4) Is submitted in the form and manner specified by CMS.

[82 FR 57103, Dec. 1, 2017]

§ 510.120 CJR participant hospital CEHRT track requirements.

(a) *CJR CEHRT use.* For performance years 2 through 8, CJR participant hospitals choose either of the following:

(1) *CEHRT use.* Participant hospitals attest in a form and manner specified by CMS to their use of CEHRT as defined in § 414.1305 of this chapter to document and communicate clinical care with patients and other health professionals.

(2) *No CEHRT use.* Participant hospitals do not attest in a form and manner specified by CMS to their use of CEHRT as defined in § 414.1305 of this chapter to document and communicate clinical care with patients and other health professionals.

(b) *Clinician financial arrangements list.* Each participant hospital that chooses CEHRT use as provided in paragraph (a)(1) of this section must submit to CMS a clinician financial arrangements list in a form and manner specified by CMS on a no more than quarterly basis. The list must include the following information on individuals and entities for the period of the CJR performance year specified by CMS:

(1) *CJR collaborators.* For each physician, nonphysician practitioner, or therapist in private practice who is a CJR collaborator during the period of the CJR performance year specified by CMS:

(i) The name, TIN, and NPI of the CJR collaborator.

(ii) The start date and, if applicable, end date, for the sharing arrangement between the CJR participant hospital and the CJR collaborator.

(2) *Collaboration agents.* For each physician, nonphysician practitioner, or therapist who is a collaboration agent during the period of the CJR performance year specified by CMS:

(i) The name and TIN of the CJR collaborator and the name, TIN, and NPI of the collaboration agent.

(ii) The start date and, if applicable, end date, for the distribution arrangement between the CJR collaborator and the collaboration agent.

(3) *Downstream collaboration agents.* For each physician, nonphysician practitioner, or therapist who is a downstream collaboration agent during the period of the CJR performance year specified by CMS—

(i) The name and TIN of the CJR collaborator and the name and TIN of the collaboration agent and the name, TIN, and NPI of the downstream collaboration agent.

(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.* Each participant hospital that chooses CEHRT use as provided in paragraph (a)(1) of this section must submit to CMS a clinician engagement list in a form and manner specified by CMS on a no more than quarterly basis. This list must include the following information on individuals for the period of the performance year specified by CMS:

(1) For each physician, nonphysician practitioner, or therapist who is not a CJR collaborator during the period of the CJR model performance year specified by CMS but who does have a contractual relationship with the participant hospital based at least in part on supporting the participant hospital's quality or cost goals under the CJR model during the period of the performance year specified by CMS:

(i) The name, TIN, and NPI of the individual.

(ii) The start date and, if applicable, the end date for the contractual relationship between the individual and participant hospital.

(2) The CJR participant hospital must retain and provide access to the required documentation in accordance with §510.110.

(d) *Attestation to no individuals.* If there are no individuals that meet the requirements to be reported, as specified in paragraphs (b)(1) through (3) or paragraph (c) of this section, the participant hospital must attest in a form and manner required by CMS that there are no individuals to report.

(e) *Documentation requirements.* (1) Each participant hospital that chooses CEHRT use as provided in paragraph (a)(1) of this section must maintain documentation of their attestation to CEHRT use, clinician financial arrangements lists, and clinician engagement lists.

(2) The participant hospital must retain and provide access to the required documentation in accordance with §510.110.

[82 FR 612, Jan. 3, 2017, as amended at 82 FR 57103, Dec. 1, 2017; 86 FR 23570, May 3, 2021]

Subpart C—Scope of Episodes

§510.200 Time periods, included and excluded services, and attribution.

(a) *Time periods.* All episodes must begin on or after April 1, 2016 and end on or before December 31, 2024.

(b) *Included services.* All Medicare Parts A and B items and services are included in the episode, except as specified in paragraph (d) 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.

(13) Hospice services.

(14) PBPM payments under models tested under section 1115A of the Act.

(15) The surgeon's Part B claim for the LEJR procedure dated within the 3 days prior to an inpatient admission, if the LEJR procedure was performed at the participant hospital on an outpatient basis but the patient was subsequently admitted as an inpatient, resulting in an anchor hospitalization.

(c) *Episode attribution.* All items and services included in the episode are attributed to the participant hospital at which the anchor hospitalization or anchor procedure, as applicable, occurs.

(d) *Excluded services.* The following items, services, and payments are excluded from the episode:

(1) Hemophilia clotting factors provided in accordance with §412.115 of this chapter.

(2) New technology add-on payments, as defined in part 412, subpart F of this chapter.

(3) Transitional pass-through payments for medical devices as defined in § 419.66 of this chapter.

(4) Items and services unrelated to the anchor hospitalization or the anchor procedure. Excluded services include, but are 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) Chronic disease surgical, such as prostatectomy.

(D) Acute disease surgical, such as appendectomy.

(ii) Medicare Part B services, as identified by the principal ICD–CM diagnosis code on the claim (based on the ICD–CM version in use during the performance year) that group to the following categories of diagnoses:

(A) Acute disease diagnoses, such as severe head injury.

(B) Certain chronic disease diagnoses, as specified by CMS on a diagnosis-by-diagnosis basis depending on whether the condition was likely to have been affected by the LEJR procedure and recovery period or whether substantial services were likely to be provided for the chronic condition during the episode. Such chronic disease diagnoses are posted on the CMS Web site and may be revised in accordance with paragraph (e) of this section.

(iii) Certain PBPM payments under models tested under section 1115A of the Act. PBPM model payments that CMS determines to be primarily used for care coordination or care management services for clinical conditions in excluded categories of diagnoses, as described in this paragraph.

(A) The list of excluded PBPM payments is posted on the CMS Web site and are revised in accordance with paragraph (e) of this section.

(B) Notwithstanding the foregoing, all PBPM model payments funded from CMS' Innovation Center appropriation are excluded from the episode.

(5) Certain incentive programs and add on payments under existing Medicare payment systems in accordance with § 510.300(b)(6) of this chapter.

(6) For performance years 1 through 4 and for performance year subsets 5.1 and 5.2, payments for otherwise included items and services in excess of 2 standard deviations above the mean regional episode payment in accordance with § 510.300(b)(5).

(7) For performance years 6 through 8 only, payments for otherwise included items and services in excess of the 99th percentile of regional spending, ranked within each region, for each of the four MS–DRG target price categories, as specified in § 510.300(a)(1) and (6), for performance years 6 through 8, in accordance with § 510.300(b)(5).

(e) *Updating the lists of excluded services.* (1) The list of excluded MS–DRGs, ICD–CM diagnosis codes, and CMS model PBPM payments are posted on the CMS Web site.

(2) For performance years 1 through 5 only, on an annual basis, or more frequently as needed, CMS updates the list of excluded services to reflect annual coding changes or other issues brought to CMS' attention.

(3) For performance years 1 through 5 only, CMS applies the following standards when revising the list of excluded services for reasons other than to reflect annual coding changes:

(i) Items or services that are directly related to the LEJR procedure or the quality or safety of LEJR care would be included in the episode.

(ii) Items or services for chronic conditions that may be affected by the LEJR procedure or post-surgical care would be related and included in the episode.

(iii) Items and services for chronic conditions that are generally not affected by the LEJR procedure or post-surgical care would be excluded from the episode.

(iv) Items and services for acute clinical conditions not arising from existing, episode-related chronic clinical conditions or complications of LEJR surgery would be excluded from the episode.

(v) PBPM payments under CMS models determined to be primarily used for care coordination or care management

services for clinical conditions in excluded categories of diagnoses, as described in § 510.200(d), would be excluded from the episode.

(4) For performance years 1 through 5 only, CMS posts the following to the CMS website:

(i) Potential revisions to the exclusion to allow for public comment; and

(ii) An updated exclusions list after consideration of public comment.

(5) For performance years 6 through 8, the list of excluded services posted on the CMS website as it appears at the beginning of performance year 5 will apply and will not be updated.

[80 FR 73540, Nov. 24, 2015, as amended at 85 FR 19292, Apr. 6, 2020; 85 FR 71199, Nov. 6, 2020; 86 FR 23570, May 3, 2021]

§ 510.205 Beneficiary inclusion criteria.

(a) Episodes tested in the CJR model include only those in which care is furnished to beneficiaries who meet all of the following criteria upon admission to the anchor hospitalization:

(1) Are enrolled in Medicare Parts A and Part B.

(2) Eligibility for Medicare is not on the basis of 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.

(6) For episodes beginning on or after July 1, 2017, are not prospectively assigned to—

(i) An ACO in the Next Generation ACO model;

(ii) An ACO in a track of the Comprehensive ESRD Care Model incorporating downside risk for financial losses; or

(iii) A Shared Savings Program ACO in the ENHANCED track (formerly Track 3).

(b) If at any time during the episode a beneficiary no longer meets all of the criteria in this section, the episode is canceled in accordance with § 510.210(b).

[80 FR 73540, Nov. 24, 2015, as amended at 82 FR 613, Jan. 3, 2017; 86 FR 23571, May 3, 2021]

§ 510.210 Determination of the episode.

(a) *General.* (1) An episode begins with the admission of a Medicare beneficiary described in § 510.205 to a participant hospital for an anchor hospitalization and ends on the 90th day after the date of discharge, with the day of discharge itself being counted as the first day in the 90-day post-discharge period.

(2) On or after July 4, 2021, an episode—

(i) Begins and ends in the manner specified in paragraph (a)(1) of this section; or

(ii) Begins on the date of service of an anchor procedure furnished to a Medicare beneficiary described in § 510.205 and ends on the 90th day after the date of service of the anchor procedure.

(b) *Cancellation of an episode.* The episode is canceled and is not included in the determination of NPRA as specified in § 510.305 if any of the following occur:

(1) The beneficiary does any of the following during the episode:

(i) Ceases to meet any criterion listed in § 510.205.

(ii) Is readmitted to any participant hospital for another anchor hospitalization, or, on or after July 4, 2021, receives an anchor procedure at any participant hospital.

(iii) Initiates an LEJR episode under BPCI.

(iv) Dies.

(2) For performance year 3, the participant hospital did not submit a participation election letter that was accepted by CMS to continue participation in the model.

[80 FR 73540, Nov. 24, 2015, as amended at 82 FR 57104, Dec. 1, 2017; 86 FR 23571, May 3, 2021]

Subpart D—Pricing and Payment

§ 510.300 Determination of episode quality-adjusted target prices.

(a) *General.* CMS establishes episode quality-adjusted target prices for participant hospitals for each performance

year or performance year subset of the model as specified in this section. Episode quality-adjusted target prices are established according to the following:

(1) *MS–DRG and fracture status.* MS–DRG assigned at discharge for anchor hospitalization and present of hip fracture diagnosis for anchor hospitalization—

(i)(A) MS–DRG 469 with hip fracture; or

(B) For episodes beginning on or after October 1, 2020, MS–DRG 521;

(ii) MS–DRG 469 without hip fracture;

(iii)(A) MS–DRG 470 with hip fracture; or

(B) For episodes beginning on or after October 1, 2020, MS–DRG 522; or

(iv) MS–DRG 470 without hip fracture.

(2) *Applicable time period for performance year or performance year subset episode quality-adjusted target prices.* For performance years 1 through 4 and performance year subset 5.1 only, episode quality-adjusted target prices are updated to account for Medicare payment updates no less than 2 times per year, for updated quality-adjusted target prices effective October 1 and January 1, and at other intervals if necessary.

(3) *Episodes that straddle performance years, performance year subsets, or payment updates.* The quality-adjusted target price that applies to the episode is one of the following:

(i) For episodes beginning on or after April 1, 2016 and ending on or before September 30, 2021, the date of admission for the anchor hospitalization.

(ii) For episodes beginning on or after July 4, 2021 and ending on or after October 1, 2021, the date of the anchor procedure or the date of admission for the anchor hospitalization, as applicable.

(4) *Identifying episodes with hip fracture.* CMS develops a list of ICD–CM hip fracture diagnosis codes that, when reported in the principal diagnosis code files on the claim for the anchor hospitalization or anchor procedure, represent a bone fracture for which a hip replacement procedure, either a partial hip arthroplasty or a total hip arthroplasty, could be the primary surgical treatment. The list of ICD–CM hip fracture diagnosis codes used to identify hip fracture episodes can be found on the CMS website. Beginning on October 1, 2020, hip fracture episodes initiated by an anchor hospitalization will be identified by MS–DRGs 521 and 522.

(i) For performance years 1 through 5 only, on an annual basis, or more frequently as needed, CMS updates the list of ICD–CM hip fracture diagnosis codes to reflect coding changes or other issues brought to CMS' attention.

(ii) For performance years 1 through 5 only, CMS applies the following standards when revising the list of ICD–CM hip fracture diagnosis codes.

(A) The ICD–CM diagnosis code is sufficiently specific that it represents a bone fracture for which a physician could determine that a hip replacement procedure, either a Partial Hip Arthroplasty (PHA) or a THA, could be the primary surgical treatment.

(B) The ICD–CM diagnosis code is the primary reason (that is, principal diagnosis code) for the anchor hospitalization.

(iii) For performance years 1 through 5 only, CMS posts the following to the CMS website:

(A) Potential ICD–CM hip fracture diagnosis codes for public comment; and

(B) A final ICD–CM hip fracture diagnosis code list after consideration of public comment.

(iv) For performance years 6 through 8, the hip fracture diagnosis code list posted at *https://innovation.cms.gov/Files/worksheets/cjr-icd10hipfracturecodes.xlsx* as it appears at the beginning of performance year 5 will not be updated. The hip fracture diagnosis code list will be used to identify hip fracture episodes initiated by an anchor procedure in performance years 6 through 8.

(5) *Quality performance.* Quality-adjusted target prices reflect effective discount factors or applicable discount factors based on a hospital's composite quality score, as specified in §§ 510.300(c) and 510.315(f).

(6) For episodes beginning on or after July 4, 2021 that are initiated by an anchor procedure, permitted OP TKAs and OP THAs are grouped with MS–DRG 470 or MS–DRG 522 episodes as follows:

(i) Permitted OP THAs with hip fracture group with MS–DRG 522.

(ii) Permitted OP THAs without hip fracture and permitted OP TKAs group with MS–DRG 470.

(b) *Episode quality-adjusted target price.* (1) CMS calculates quality-adjusted target prices based on a blend of each participant hospital's hospital-specific and regional episode expenditures. The region corresponds to the U.S. Census Division associated with the primary address of the CCN of the participant hospital and the regional component is based on all hospitals in said region, except as follows. In cases where an MSA selected for participation in CJR spans more than one U.S. Census Division, the entire MSA will be grouped into the U.S. Census Division where the largest city by population in the MSA is located for quality-adjusted target price and reconciliation calculations. The calendar years used for historical expenditure calculations are as follows:

(i) Episodes beginning in 2012 through 2014 for performance years 1 and 2.

(ii) Episodes beginning in 2014 through 2016 for performance years 3 and 4.

(iii) Episodes beginning in 2016 through 2018 for each of performance year subsets 5.1 and 5.2.

(iv) Episodes beginning in 2019 for performance year 6.

(v) Episodes beginning in 2021 for performance year 7.

(vi) Episodes beginning in 2022 for performance year 8.

(2) Specifically, the blend consists of the following:

(i) Two-thirds of the participant hospital's own historical episode payments and one-third of the regional historical episode payments for performance years 1 and 2.

(ii) One-third of the hospital's own historical episode payments and two-thirds of the regional historical episode payments for performance year 3.

(iii) Regional historical episode payments for performance year 4, for each subset of performance year 5, and performance years 6 through 8.

(3) *Exception for low-volume hospitals.* Quality-adjusted target prices for participant hospitals with fewer than 20 CJR episodes in total across the 3 historical years of data used to calculate the quality-adjusted target price are based on 100 percent regional historical episode payments.

(4) *Exception for recently merged or split hospitals.* Hospital-specific historical episode payments for participant hospitals that have undergone a merger, consolidation, spin off or other reorganization that results in a new hospital entity without 3 full years of historical claims data are determined using the historical episode payments attributed to their predecessor(s).

(5) *Exception for high episode spending.* (i) For performance years 1 through 4, and for performance year 5, each subset thereof, episode payments are capped at 2 standard deviations above the mean regional episode payment for both the hospital-specific and regional components of the quality-adjusted target price.

(ii) For performance years 6 through 8, episode payments are capped at the 99th percentile of regional spending for each of the four MS–DRG categories, as specified in §510.300(a)(1) and (6).

(6) *Exclusion of incentive programs and add-on payments under existing Medicare payment systems.* Certain incentive programs and add-on payments are excluded from historical episode payments 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.

(7) *Communication of episode quality-adjusted target prices.* CMS communicates episode quality-adjusted target prices to participant hospitals before the performance period in which they apply.

(8) *Inclusion of reconciliation payments and repayments.* For performance years 3, 4, and each of performance year subsets 5.1 and 5.2 only, reconciliation payments and repayment amounts under §510.305(f)(2) and (3) and from LEJR episodes included in the BPCI initiative are included in historical episode payments.

(c) *Discount factor.* A participant hospital's episode quality-adjusted target prices incorporate discount factors to reflect Medicare's portion of reduced expenditures from the CJR model as described in this section.

(1) *Discount factors affected by the quality incentive payments and the composite quality score.* In all performance years and performance year subsets, the discount factor may be affected by the quality incentive payment and composite quality score as provided in § 510.315 to create the effective discount factor or applicable discount factor used for calculating reconciliation payments and repayment amounts. The quality-adjusted target prices incorporate the effective or applicable discount factor at reconciliation.

(2) *Discount factor for reconciliation payments.* The discount factor for reconciliation payments in all performance years and performance year subsets is 3.0 percent.

(3) *Discount factors for repayment amounts.* The discount factor for repayment amounts is—

(i) Not applicable in performance year 1, as the requirement for hospital repayment under the CJR model is waived in performance year 1;

(ii) In performance years 2 and 3, 2.0 percent; and

(iii) In performance years 4, each subset of performance year 5, and performance years 6 through 8, 3.0 percent.

(d) *Data sharing.* (1) CMS makes available to participant hospitals, through the most appropriate means, data that CMS determines may be useful to participant hospitals to do the following:

(i) Determine appropriate ways to increase the coordination of care.

(ii) Improve quality.

(iii) Enhance efficiencies in the delivery of care.

(iv) Otherwise achieve the goals of the CJR model described in this section.

(2) *Beneficiary-identifiable data.* (i) CMS makes beneficiary-identifiable data available to a participant hospital in accordance with applicable privacy laws and only in response to the hospital's request for such data for a beneficiary who has been furnished a billable service by the participant hospital corresponding to the episode definitions for CJR.

(ii) The minimum data necessary to achieve the goals of the CJR model, as determined by CMS, may be provided under this section for a participant hospital's baseline period and no less frequently than on a quarterly basis throughout the hospital's participation in the CJR model.

[80 FR 73540, Nov. 24, 2015, as amended at 81 FR 11451, Mar. 4, 2016; 82 FR 613, Jan. 3, 2017; 82 FR 57104, Dec. 1, 2017; 85 FR 71199, Nov. 6, 2020; 86 FR 23571, May 3, 2021]

§ 510.301 Determination of reconciliation target prices.

Beginning with performance year 6, the quality-adjusted target price computed under § 510.300 is further adjusted for risk and market trends as described in this section to arrive at the reconciliation target price amount, with the exception of episodes that are reconciled in performance year 6 but subject to a performance year subset 5.2 target price. Specifically:

(a) *Risk adjustment.* (1) The quality-adjusted target prices computed under § 510.300 are risk adjusted at a beneficiary level by a CJR HCC count risk adjustment factor, an age bracket risk adjustment factor, and a dual-eligibility status risk adjustment factor. All three factors are binary, yes/no variables, meaning that a beneficiary either does or does not meet the criteria for a specific variable.

(i) The CJR HCC count risk adjustment factor uses five variables, representing beneficiaries with zero, one, two, three, or four or more CMS–HCC conditions.

(ii) The age bracket risk adjustment factor uses four variables, representing beneficiaries aged—

(A) Less than 65 years;

(B) 65 to 74 years;

(C) 75 years to 84 years; or

(D) 85 years or more.

(iii) The dual-eligibility status factor uses two variables, representing beneficiaries that are eligible for full Medicaid benefits or beneficiaries that are not eligible for full Medicaid benefits.

(2) All three factors are computed prior to the start of performance years 6 and 8 via a linear regression analysis. The regression analysis is computed using 1 year of claims data as follows:

(i) For performance year 6, CMS uses claims data with dates of service dated January 1, 2019 to December 31, 2019.

(ii) For performance year 7, CMS uses the same regression analysis results

and corresponding coefficients that were calculated for performance year 6.

(iii) For performance year 8, CMS uses claims data with dates of service dated January 1, 2021 to December 31, 2021.

(3)(i) The dependent variable in the annual regression that produces the risk adjustment coefficients is equal to the difference between the log transformed target price calculated under § 510.300 and the capped episode costs as described in § 510.300(b)(5)(ii).

(ii) The independent variables are binary values assigned to each CJR HCC count variable, age bracket variable and dual-eligibility status variable.

(iii) Using these variables, the annual regression produces exponentiated coefficients to determine the anticipated marginal effect of each risk adjustment factor on episode costs. CMS transforms, or exponentiate, these coefficients in order to ''reverse'' the previous logarithmic transformation, and the resulting coefficients are the CJR HCC count risk adjustment factor, the age bracket risk adjustment factor, and the dual-eligibility status factor that would be used during reconciliation for the subsequent performance year.

(4)(i) At the time of reconciliation, the quality adjusted target prices computed under § 510.300 are risk adjusted at the beneficiary level by applying the applicable CJR HCC count risk adjustment factor, the age bracket risk adjustment factor, and the dual-eligibility risk adjustment factor specific to the beneficiary in the episode.

(ii)(A) For the CJR HCC count risk adjustment factor, applicable means the coefficient that applies to the CMS–HCC condition count for the beneficiary in the episode;

(B) For the age bracket risk adjustment factor, applicable means the coefficient for the age bracket into which the beneficiary falls on the first day of the episode; and

(C) For the dual-eligibility risk adjustment factor, applicable means the coefficient for beneficiaries that are eligible for full Medicaid benefits on the first day of the episode.

(5)(i) The risk-adjusted target prices are normalized at reconciliation to remove the overall impact of adjusting for age, CJR HCC count, and dual-eligibility status on the national average target price.

(ii) The normalization factor is the national mean of the target price for all episode types divided by the national mean of the risk-adjusted target price.

(iii) CMS applies the normalization factor to the previously calculated, beneficiary-level, risk-adjusted target prices specific to each episode region and MS–DRG combination (as specified in paragraph (a)(4) of this section).

(iv) These normalized target prices are then further adjusted for market trends (as specified in paragraph (b) of this section) and quality performance (as specified at § 510.300) to become the reconciliation target prices, which are compared to actual episode costs at reconciliation, as specified in § 510.305(m)(1)(i).

(b) *Market trend adjustment factor*. (1) The risk-adjusted quality-adjusted target price computed under § 510.300 and paragraph (a) of this section is further adjusted for market trend changes at the region and MS–DRG level.

(2) This adjustment is accomplished by multiplying each risk-adjusted quality-adjusted target price computed under § 510.300 and paragraph (a) of this section by the applicable market trend adjustment factor.

(3) The applicable market trend adjustment factor is calculated as the percent difference between the average regional MS–DRG episode costs computed using the performance year claims data and comparison average regional MS–DRG fracture episode costs computed using historical calendar year claims data used to calculate the regional target prices in effect for that performance year.

[86 FR 23571, May 3, 2021]

§ 510.305 Determination of the NPRA and reconciliation process.

(a) *General*. Providers and suppliers furnishing items and services included in the episode bill for such items and services in accordance with existing rules and as if this part were not in effect.

(b) *Reconciliation*. (1) For performance years 1 through 4 and for each subset of performance year 5, CMS uses a series

of reconciliation processes, which CMS performs as described in paragraphs (d) and (f) of this section after the end of each performance year, to establish final payment amounts to participant hospitals for CJR model episodes for a given performance year.

(2) For performance years 6 through 8, CMS conducts one reconciliation process, which CMS performs as described in paragraphs (l) and (m) of this section after the end of each performance year, to establish final payment amounts to participant hospitals for CJR model episodes for a given performance year.

(3) Following the end of each performance year, for performance years 1 through 4 and for performance year 5, each subset thereof, CMS determines actual episode payments for each episode for the performance year (other than episodes that have been canceled in accordance with §510.210(b)) and determines the amount of a reconciliation payment or repayment amount.

(c) *Data used.* CMS uses the most recent claims data available to perform each reconciliation calculation.

(d) *Annual reconciliation for performance years 1 through 5.* (1) Beginning 2 months after the end of each of performance years 1 through 4 and performance year subset 5.1 and 5 months after the end of performance year subset 5.2, CMS does all of the following:

(i) Performs a reconciliation calculation to establish an NPRA for each participant hospital.

(ii) For participant hospitals that experience a reorganization event in which one or more hospitals reorganize under the CCN of a participant hospital performs—

(A) Separate reconciliation calculations (during both initial and subsequent reconciliations for a performance year) for each predecessor participant hospital for episodes where anchor hospitalization admission occurred before the effective date of the reorganization event; and

(B) Reconciliation calculations (during both initial and subsequent reconciliations for a performance year) for each new or surviving participant hospital for episodes where the anchor hospitalization admission occurred on or after the effective date of the reorganization event.

(2) CMS—

(i) Calculates the NPRA for each participant hospital in accordance with paragraph (e) of this section including the adjustments provided for in paragraph (e)(1)(iv) of this section; and

(ii) Assesses whether hospitals meet specified quality requirements under §510.315.

(e) *Calculation of the NPRA for performance years 1 through 5.* By comparing the quality-adjusted target prices described in §510.300 and the participant hospital's actual episode spending for each of performance years 1 through 4, and for performance year 5, each subset thereof, and applying the adjustments in paragraph (e)(1)(v) of this section, CMS establishes an NPRA for each participant hospital for each of performance years 1 through 4 and for performance year 5, each subset thereof.

(1) *Initial calculation.* In calculating the NPRA for each participant hospital for each of performance years 1 through 4 and each of performance year subsets 5.1 and 5.2, CMS does the following:

(i) Determines actual episode payments for each episode included in the performance year or performance year subset (other than episodes that have been canceled in accordance with §510.210(b)) using claims data that is available 2 months after the end of the performance year or performance year subset. Actual episode payments are capped, as applicable, at the amount determined in accordance with §510.300(b)(5) for the performance year or performance year subset at the amount determined in paragraph (k) of this section for episodes affected by extreme and uncontrollable circumstances, or at the quality adjusted target price determined for that episode under §510.300 for an episode with actual episode payments that include a claim with a COVID–19 diagnosis code and initiate after the earlier of March 31, 2021 or the last day of the emergency period described in paragraph (k)(4) of this section.

(ii) Multiplies each episode quality-adjusted target price by the number of episodes included in the performance

year or performance year subset (other than episodes that have been canceled in accordance with §510.210(b)) to which that episode quality-adjusted target price applies.

(iii) Aggregates the amounts computed in paragraph (e)(1)(ii) of this section for all episodes included in the performance year or performance year subset (other than episodes that have been canceled in accordance with §510.210(b)).

(iv) Subtracts the amount determined under paragraph (e)(1)(i) of this section from the amount determined under paragraph (e)(1)(iii) of this section.

(v) Applies the following prior to determination of the reconciliation payment or repayment amount:

(A) *Limitation on loss.* Except as provided in paragraph (e)(1)(v)(C) of this section, the total amount of the NPRA and subsequent reconciliation calculation for a performance year or performance year subset cannot exceed the following:

(*1*) For performance year 2 only, 5 percent of the amount calculated in paragraph (e)(1)(iii) of this section for the performance year.

(*2*) For performance year 3, 10 percent of the amount calculated in paragraph (e)(1)(iii) of this section for the performance year.

(*3*) For performance year 4 and each of performance year subsets 5.1 and 5.2, 20 percent of the amount calculated in paragraph (e)(1)(iii) of this section for the performance year or performance year subset.

(*4*) As provided in paragraph (i) of this section, the subsequent reconciliation calculation reassesses the limitation on loss for a given performance year by applying the limitations on loss to the aggregate of the 2 reconciliation calculations.

(*5*) The post-episode spending and ACO overlap calculation amounts in paragraphs (j)(1) and (2) of this section are not subject to the limitation on loss.

(B) *Limitation on gain.* The total amount of the NPRA and subsequent reconciliation calculation for a performance year or performance year subset cannot exceed the following:

(*1*) For performance years 1 and 2, 5 percent of the amount calculated in paragraph (e)(1)(iii) of this section for the performance year.

(*2*) For performance year 3, 10 percent of the amount calculated in paragraph (e)(1)(iii) of this section for the performance year.

(*3*) For performance year 4 and each of performance year subsets 5.1 and 5.2, 20 percent of the amount calculated in paragraph (e)(1)(iii) of this section for the performance year or performance year subset.

(*4*) As provided in paragraph (i) of this section, the subsequent reconciliation calculation reassesses the limitation on gain for a given performance year by applying the limitations on gain to the aggregate of the 2 reconciliation calculations.

(*5*) The post-episode spending and ACO overlap calculation amounts in paragraphs (j)(1) and (j)(2) of this section are not subject to the limitation on gain.

(C) *Financial loss limits for rural hospitals, SCHs, MDHs, and RRCs.* If a participant hospital is a rural hospital, SCH, MDH, or RRC, then for performance year 2, the total repayment amount for which the participant hospital is responsible due to the NPRA and subsequent reconciliation calculation cannot exceed 3 percent of the amount calculated in paragraph (e)(1)(iii) of this section. For performance years 3 and 4 and for performance year subsets 5.1 and 5.2, the amount cannot exceed 5 percent of the amount calculated in paragraph (e)(1)(iii) of this section.

(f) *Determination of reconciliation or repayment amount*—(1) *Determination of the reconciliation or repayment amount.* (i) Subject to paragraph (f)(1)(iii) of this section, for performance year 1, the reconciliation payment (if any) is equal to the NPRA.

(ii) Subject to paragraph (f)(1)(iii) of this section, for performance years 2 through 4 and for each of performance year subsets 5.1 and 5.2, results from the subsequent reconciliation calculation for a prior year's reconciliation as described in paragraph (i) of this section and the post-episode spending and ACO overlap calculations as described in paragraph (j) of this section are

added to the current year's NPRA in order to determine the reconciliation payment or repayment amount.

(iii) The reconciliation or repayment amount may be adjusted as provided in § 510.410(b).

(iv) Results from the performance year 6 reconciliation and post-episode spending calculations as described in paragraph (m) of this section are added together in order to determine the reconciliation payment or repayment amount for performance year 6.

(v) Results from the performance year 7 reconciliation and post-episode spending calculations as described in paragraph (m) of this section are added together in order to determine the reconciliation payment or repayment amount for performance year 7.

(vi) Results from the performance year 8 reconciliation and post-episode spending calculations as described in paragraph (m) of this section are added together in order to determine the reconciliation payment or repayment amount for performance year 8.

(2) *Reconciliation payment.* If the amount described in paragraph (f)(1) of this section is positive and the composite quality score described in § 510.315 is acceptable (defined as greater than or equal to 5.00 and less than 6.9), good (defined as greater than or equal to 6.9 and less than or equal to 15.0), or excellent (defined as greater than 15.0), Medicare pays the participant hospital a reconciliation payment in an amount equal to the amount described in paragraph (f)(1) of this section.

(3) *Repayment amount.* If the amount described in paragraph (f)(1) of this section is negative, the participant hospital pays to Medicare an amount equal to the amount described in paragraph (f)(1) of this section, in accordance with § 405.371 of this chapter. CMS waives this requirement for performance year 1.

(g) *Determination of eligibility for reconciliation based on quality.* (1) CMS assesses each participant hospital's performance on quality metrics, as described in § 510.315, to determine whether the participant hospital is eligible to receive a reconciliation payment for a performance year or performance year subset.

(2) If the hospital's composite quality score described in § 510.315 is acceptable (defined as greater than or equal to 5.00 and less than 6.9), good (defined as greater than or equal to 6.9 and less than or equal to 15.0), or excellent (defined as greater than 15.0), and the hospital is determined to have a positive NPRA under § 510.305(e)), the hospital is eligible for a reconciliation payment.

(3) If the hospital's composite quality score described in § 510.315 is below acceptable, defined as less than 4.00 for a performance year or performance year subset, the hospital is not eligible for a reconciliation payment.

(4) If the hospital is found to be engaged in an inappropriate and systemic under delivery of care, the quality of the care provided must be considered to be seriously compromised and the hospital must be ineligible to receive or retain a reconciliation payment for any period in which such under delivery of care was found to occur.

(h) *Reconciliation report.* CMS issues each participant hospital a CJR reconciliation report for the performance year or performance year subset. Each CJR reconciliation report contains the following:

(1) Information on the participant hospital's composite quality score described in § 510.315.

(2) The total actual episode payments for the participant hospital.

(3) The NPRA.

(4) Whether the participant hospital is eligible for a reconciliation payment or must make a repayment to Medicare.

(5) As applicable, the NPRA and subsequent reconciliation calculation amount for the previous performance year or performance year subset.

(6) As applicable, the post-episode spending amount and ACO overlap calculation for the previous performance year or performance year subset.

(7) The reconciliation payment or repayment amount.

(i) *Subsequent reconciliation calculation.* (1) Fourteen months after the end of each of performance years 1 through 4 and performance year subset 5.1 and seventeen months after the end of performance year subset 5.2, CMS performs an additional calculation, using claims data available at that time, to

account for final claims run-out and any additional episode cancelations due to overlap between the CJR model and other CMS models and programs, or for other reasons as specified in § 510.210(b).

(2) The subsequent calculation for each of performance years 1 through 4 and performance year subset 5.1 occurs concurrently with the first reconciliation process for the following performance year (or in the case of performance year subset 5.1, with the first reconciliation of performance year subset 5.2). If the result of the subsequent calculation is different than zero, CMS applies the stop-loss and stop-gain limits in paragraph (e) of this section to the aggregate calculation of the amounts described in paragraphs (e)(1)(iv) and (i)(1) of this section for that performance year or performance year subset (the initial reconciliation and the subsequent reconciliation calculation) to ensure such amount does not exceed the applicable stop-loss or stop-gain limits. The subsequent reconciliation calculation for performance year subset 5.2 will occur independently in 2023.

(j) *Additional adjustments to the reconciliation payment or repayment amount.* (1) In order to account for shared savings payments, CMS will reduce the reconciliation payment or increase the repayment amount for the subsequent performance year (for performance years 1 through 4 and performance year subset 5.1) by the amount of the participant hospital's discount percentage that is paid to the ACO in the prior performance year as shared savings. (This amount will be assessed independently for performance year subset 5.2 in 2023.) This adjustment is made only when the participant hospital is a participant or provider/supplier in the ACO and the beneficiary in the CJR episode is assigned to one of the following ACO models or programs:

(i) The Pioneer ACO model.

(ii) The Medicare Shared Savings Program (excluding Track 3 for CJR episodes that initiate on or after July 1, 2017).

(iii) The Comprehensive ESRD Care Initiative (excluding a track with downside risk for CJR episodes that initiate after July 1, 2017).

(iv) The Next Generation ACO model (excluding CJR episodes that initiate on or after July 1, 2017).

(2) If the average post-episode Medicare Parts A and B payments for a participant hospital in the prior performance year or performance year subset is greater than 3 standard deviations above the regional average post-episode payments for the same performance year or performance year subset, then the spending amount exceeding 3 standard deviations above the regional average post-episode payments for the same performance year or performance year subset is subtracted from the net reconciliation or added to the repayment amount for the subsequent performance year for years 1 through 4 and performance year subset 5.1, and assessed independently for performance year subset 5.2.

(k) *Extreme and uncontrollable circumstances adjustment.* (1) The episode spending adjustments specified in paragraph (k)(2) of this section apply for a participant hospital that has a CCN primary address that meets both of the following:

(i) Is located in an emergency area during an emergency period, as those terms are defined in section 1135(g) of the Act, for which the Secretary has issued a waiver under section 1135; and

(ii) Is located in a county, parish, or tribal government designated in a major disaster declaration under the Stafford Act.

(2)(i) For a non-fracture episode with a date of admission to the anchor hospitalization that is on or within 30 days before the date that the emergency period (as defined in section 1135(g) of the Act) begins, actual episode payments are capped at the target price determined for that episode under § 510.300.

(ii) For a fracture episode with a date of admission to the anchor hospitalization that is on or within 30 days before or after the date that the emergency period (as defined in section 1135(g) of the Act) begins, actual episode payments are capped at the target price determined for that episode under § 510.300.

(3) The following is an extreme and uncontrollable circumstances adjustment for 2019 Novel Coronavirus (previously referred to as 2019–nCoV, now as COVID–19):

(i) The episode spending adjustments specified in paragraph (k)(4) of this section apply for a participant hospital that has a CCN primary address that is located in an emergency area during an emergency period, as those terms are defined in section 1135(g) of the Act, for which the Secretary issued a waiver or modification of requirements under section 1135 of the Act on March 13, 2020.

(ii) [Reserved]

(4) For a fracture or non-fracture episode with a date of admission to the anchor hospitalization that is on or within 30 days before the date that the emergency period (as defined in section 1135(g) of the Act) begins or that occurs on or before March 31, 2021 or the last day of such emergency period, whichever is earlier, actual episode payments are capped at the quality adjusted target price determined for that episode under § 510.300.

(l) *Annual reconciliation for performance years 6 through 8.* (1) Beginning 6 months after the end of each of performance years 6 through 8, CMS does all of the following:

(i) Performs a reconciliation calculation to establish an NPRA for each participant hospital.

(ii) For participant hospitals that experience a reorganization event in which one or more hospitals reorganize under the CCN of a participant hospital, performs—

(A) Separate reconciliation calculations for each predecessor participant hospital for episodes where the anchor hospitalization admission or the anchor procedure occurred before the effective date of the reorganization event; and

(B) Reconciliation calculations for each new or surviving participant hospital for episodes where the anchor hospitalization admission or anchor procedure occurred on or after the effective date of the reorganization event.

(2) CMS—

(i) Calculates the NPRA for each participant hospital in accordance with paragraph (m) of this section including the adjustments provided for in paragraph (m)(1)(vii) of this section; and

(ii) Assesses whether participant hospitals meet specified quality requirements under § 510.315.

(m) *Calculation of the NPRA for performance years 6 through 8.* By comparing the reconciliation target prices described in § 510.301 and the participant hospital's actual episode spending for the performance year and applying the adjustments in paragraph (m)(1)(vii) of this section, CMS establishes an NPRA for each participant hospital for each of performance years 6 through 8.

(1) In calculating the NPRA for each participant hospital for each performance year, CMS does the following:

(i) Determines actual episode payments for each episode included in the performance year (other than episodes that have been canceled in accordance with § 510.210(b)) using claims data that is available 6 months after the end of the performance year. Actual episode payments are capped at the amount determined in accordance with § 510.300(b)(5)(ii) for the performance year, the amount determined in paragraph (k) of this section for episodes affected by extreme and uncontrollable circumstances, or the target price determined for that episode under § 510.300 for episodes that contain a COVID–19 Diagnosis Code as defined in § 510.2.

(ii) Multiplies each episode reconciliation target price by the number of episodes included in the performance year (other than episodes that have been canceled in accordance with § 510.210(b)) to which that episode reconciliation target price applies.

(iii) Aggregates the amounts computed in paragraph (m)(1)(ii) of this section for all episodes included in the performance year (other than episodes that have been canceled in accordance with § 510.210(b)).

(iv) Subtracts the amount determined under paragraph (m)(1)(i) of this section from the amount determined under paragraph (m)(1)(iii) of this section.

(v) Performs an additional calculation using claims data available at that time, to account for any episode

cancelations due to overlap between the CJR model and other CMS models and programs, or for other reasons as specified in §510.210(b).

(vi) Conducts a post-episode spending calculation as follows: If the average post-episode Medicare Parts A and B payments for a participant hospital in the performance year being reconciled is greater than 3 standard deviations above the regional average post-episode payments for that same performance year, then the spending amount exceeding 3 standard deviations above the regional average post-episode payments for the same performance year is subtracted from the net reconciliation or added to the repayment for that performance year.

(vii) Applies the following prior to determination of the reconciliation payment or repayment amount:

(A) *Limitation on loss.* Except as provided in paragraph (m)(1)(vii)(C) of this section, the total amount of the NPRA for a performance year cannot exceed 20 percent of the amount calculated in paragraph (m)(1)(iii) of this section for the performance year. The post-episode spending calculation amount in paragraph (m)(vi) of this section is not subject to the limitation on loss.

(B) *Limitation on gain.* The total amount of the NPRA for a performance year cannot exceed 20 percent of the amount calculated in paragraph (m)(1)(iii) of this section for the performance year. The post-episode spending calculation amount in paragraph (m)(vi) of this section are not subject to the limitation on gain.

(C) *Limitation on loss for certain providers.* Financial loss limits for rural hospitals, SCHs, MDHs, and RRCs for performance years 6 through 8. If a participant hospital is a rural hospital, SCH, MDH, or RRC, the amount cannot exceed 5 percent of the amount calculated in paragraph (m)(1)(iii) of this section.

(2) [Reserved]

[80 FR 73540, Nov. 24, 2015, as amended at 81 FR 11451, Mar. 4, 2016; 82 FR 613, Jan. 3, 2017; 82 FR 57104, Dec. 1, 2017; 85 FR 19292, Apr. 6, 2020; 85 FR 71199, Nov. 6, 2020; 86 FR 23572, May 3, 2021]

EDITORIAL NOTE: At 86 FR 23572, May 3, 2021, §510.305 was amended in part by revising paragraph (i); however, the amendment could not be incorporated due to inaccurate amendatory instruction.

§510.310 Appeals process.

(a) *Notice of calculation error (first level of appeal).* Subject to the limitations on review in subpart D of this part, if a participant hospital 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 participant hospital is required to provide written notice of the calculation error, in a form and manner specified by CMS.

(1) Unless the participant hospital provides such notice, CMS deems final the CJR reconciliation report 45 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 45 calendar days of the issuance of the 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, although CMS reserves the right to an extension upon written notice to the participant hospital.

(3) Only participant hospitals may use the dispute resolution process described in this part.

(4) Only participant hospitals may use the notice of calculation error process described in this part.

(b) *Dispute resolution process (second level of appeal).* (1) If the participant hospital is dissatisfied with CMS's response to the notice of a calculation error, the participant hospital may request a reconsideration review in a form and manner as specified by CMS.

(2) The reconsideration review request must provide a detailed explanation of the basis for the dispute and include supporting documentation for the participant hospital's assertion that CMS or its representatives did not accurately calculate the NPRA, the reconciliation payment, or the repayment amount in accordance with §510.305.

(3) If CMS does not receive a request for reconsideration from the participant hospital within 10 calendar days of the issue date of CMS's response to the participant hospital's notice of calculation error, then CMS's response to the calculation error is deemed final and CMS proceeds with reconciliation payment or repayment processes, as applicable, as described in § 510.305.

(4) A CMS reconsideration official notifies the participant hospital in writing within 15 calendar days of receiving the participant hospital's review request of the following:

(i) The issues in dispute.

(ii) The review procedures.

(iii) The procedures (including format and deadlines) for submission of briefs and evidence.

(5) The provisions at § 425.804(b), (c), and (e) of this chapter are applicable to reviews conducted in accordance with the reconsideration review process for CJR.

(6) The CMS reconsideration official makes all reasonable efforts to issue a written determination within 30 days of the deadline for submission of briefs and evidence. The determination is final and binding.

(c) *Exception to the process.* If the participant hospital contests a matter that does not involve an issue contained in, or a calculation that contributes to, a CJR reconciliation report, a notice of calculation error is not required. In these instances, if CMS does not receive a request for reconsideration from the participant hospital within 10 calendar days of the notice of the initial determination, the initial determination is deemed final and CMS proceeds with action indicated in the initial determination. This does not apply to the limitations on review in paragraph (e) of this section.

(d) *Notice of a participant hospital's termination from the CJR model.* If a participant hospital receives notification that it has been terminated from the CJR model, it must provide a written notice to CMS requesting review of the termination within 10 calendar days of the notice. CMS has 30 days to respond to the participant hospital's request for review. If the participant hospital fails to notify CMS, the termination is deemed final.

(e) *Limitations on review.* In accordance with section 1115A(d)(2) of the Act, there is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for the following:

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

(2) The selection of organizations, sites, or participants to test those models selected.

(3) The elements, parameters, scope, and duration of such models for testing or dissemination.

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

(5) The termination or modification of the design and implementation of a model under section 1115A(b)(3)(B) of Act.

(6) Decisions about expansion of the duration and scope of a model under section 1115A(c) of the Act, including the determination that a model is not expected to meet criteria described in section 1115A(c)(1) or (2) of the Act.

[80 FR 73540, Nov. 24, 2015, as amended at 82 FR 615, Jan. 3, 2017; 86 FR 23573, May 3, 2021]

§ 510.315 Composite quality scores for determining reconciliation payment eligibility and quality incentive payments.

(a) *General.* A participant hospital's eligibility for a reconciliation payment under § 510.305(g), and the determination of quality incentive payments under paragraph (f) of this section, for a performance year or performance year subset depend on the hospital's composite quality score (including any quality performance points and quality improvement points earned) for that performance year or performance year subset.

(b) *Composite quality score.* CMS calculates a composite quality score for each participant hospital for each performance year or performance year subset which equals the sum of the following:

(1) The hospital's quality performance points for the hospital-level risk-standardized complication rate following elective primary total hip arthroplasty and/or total knee

arthroplasty measure (NQF #1550) described in §510.400(a)(1). This measure is weighted at 50 percent of the composite quality score.

(2) The hospital's quality performance points for the Hospital Consumer Assessment of Healthcare Providers and Systems Survey measure (NQF #0166) described in §510.400(a)(2). This measure is weighted at 40 percent of the composite quality score.

(3) Any additional quality improvement points the hospital may earn as a result of demonstrating improvement on either or both of the quality measures in paragraphs (b)(1) and (2) of this section, as described in paragraph (d) of this section.

(4) If applicable, 2 additional points for successful THA/TKA voluntary data submission of patient-reported outcomes and limited risk variable data, as described in §510.400(b). Successful submission is weighted at 10 percent of the composite quality score.

(c) *Quality performance points.* CMS computes quality performance points for each quality measure based on the participant hospital's performance relative to the distribution of performance of all subsection (d) hospitals that are eligible for payment under IPPS and meet the minimum patient case or survey count for that measure.

(1) For the hospital-level risk-standardized complication rate following elective primary total hip arthroplasty and/or total knee arthroplasty measure (NQF #1550) described in §510.400(a)(1), CMS assigns the participant hospital measure value to a performance percentile and then quality performance points are assigned based on the following performance percentile scale:

(i) 10.00 points for ≥90th.

(ii) 9.25 points for ≥80th and <90th.

(iii) 8.50 points for ≥70th and <80th;

(iv) 7.75 points for ≥60th and <70th.

(v) 7.00 points for ≥50th and <60th.

(vi) 6.25 points for ≥40th and <50th.

(vii) 5.50 points for ≥30th and <40th.

(viii) 0.0 points for <30th.

(2) For the Hospital Consumer Assessment of Healthcare Providers and Systems Survey measure (NQF #0166) described in §510.400(a)(2), CMS assigns the participant hospital measure value to a performance percentile and quality performance points are assigned based on the following performance percentile scale:

(i) 8.00 points for ≥90th.

(ii) 7.40 points for ≥80th and <90th.

(iii) 6.80 points for ≥70th and <80th.

(iv) 6.20 points for ≥60th and <70th.

(v) 5.60 points for ≥50th and <60th.

(vi) 5.00 points for ≥40th and <50th.

(vii) 4.40 points for ≥30th and <40th.

(viii) 0.0 points for <30th.

(d) *Quality improvement points.* (1) For performance year 1, if a participant hospital's quality performance percentile on an individual measure described in §510.400(a) increases from the corresponding time period in the previous year by at least 2 deciles on the performance percentile scale, then the hospitals is eligible to receive quality improvement points equal to 10 percent of the total available point for that individual measure up to a maximum composite quality score of 20 points.

(2) For each of performance years 2 through 4, each of performance year subsets 5.1 and 5.2, and each of performance years 6 through 8, if a participant hospital's quality performance percentile on an individual measure described in §510.400(a) increases from the previous performance year or performance year subset by at least 2 deciles on the performance percentile scale, then the hospital is eligible to receive quality improvement points equal to 10 percent of the total available point for that individual measure up to a maximum composite quality score of 20 points.

(e) *Exception for hospitals without a measure value.* In the case of a participant hospital without a measure value that would allow CMS to assign quality performance points for that quality measure, CMS assigns the 50th percentile quality performance points to the hospital for the individual measure.

(1) A participant hospital will not have a measure value for the—

(i) Hospital-level risk-standardized complication rate following elective primary total hip arthroplasty and/or total knee arthroplasty measure (NQF #1550) described in §510.400(a)(1) if the hospital does not meet the minimum 25 case count; or

(ii) Hospital Consumer Assessment of Healthcare Providers and Systems Survey measure (NQF #0166) described in § 510.400(a)(2) if the hospital does not meet the minimum of 100 completed survey and does not have 4 consecutive quarters of HCAHPS data.

(ii) For either of the measures described in paragraphs (e)(1) or (2) of this section, if CMS identifies an error in the data used to calculate the measure and suppresses the measure value.

(f) *Quality incentive payments.* CMS provides incentive payments to participant hospitals that demonstrate good or excellent quality performance on the composite quality scores described in paragraph (b) of this section. These incentive payments are implemented in the form of the following reductions to the effective discount factors or applicable discount factors described in § 510.300(c):

(1) *Performance years 1 through 5.* For performance years 1 through 5—

(i) A 1.0 percentage point reduction to the effective discount factor or applicable discount factor for participant hospitals with good quality performance, defined as composite quality scores that are greater than or equal to 6.9 and less than or equal to 15.0; or

(ii) A 1.5 percentage point reduction to the effective discount factor or applicable discount factor for participant hospitals with excellent quality performance, defined as composite quality scores that are greater than 15.0.

(2) *Performance years 6 through 8.* For performance years 6 through 8—

(i) A 1.5-percentage point reduction to the effective discount factor or applicable discount factor for participant hospitals with good quality performance, defined as composite quality scores that are greater than or equal to 6.9 and less than or equal to 15.0; or

(ii) A 3-percentage point reduction to the effective discount factor or applicable discount factor for participant hospitals with excellent quality performance, defined as composite quality scores that are greater than 15.0.

[80 FR 73540, Nov. 24, 2015, as amended at 82 FR 615, Jan. 3, 2017; 85 FR 71201, Nov. 6, 2020; 86 FR 23573, May 3, 2021]

§ 510.320 Treatment of incentive programs or add-on payments under existing Medicare payment systems.

The CJR model does not replace any existing Medicare incentive programs or add-on payments. The target price and NPRA for a participant hospital are independent of, and do not affect, any incentive programs or add-on payments under existing Medicare payment systems.

§ 510.325 Allocation of payments for services that straddle the episode.

(a) *General.* Services included in the episode that straddle the episode are prorated so that only the portion attributable to care furnished during the episode are included in the calculation of actual episode payments.

(b) *Proration of services.* Payments for services that straddle the episode are prorated using the following methodology:

(1) *Non-IPPS inpatient services and other inpatient services.* Non-IPPS inpatient services, and services furnished by other inpatient providers 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 services paid under the prospective payment system in part 484, subpart E of this chapter are prorated according to the percentage of days, starting with the first billable service date (''start of care date'') and through and including the last billable service date, that occur during the episode. This methodology is applied in the same way if the home health services begin (the start of care date) prior to the start of the episode.

(3) *IPPS services.* IPPS claim amounts that extend beyond the end of the episode are prorated according to the 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 normal MS–DRG payment is fully allocated to the episode.

(iii) If the actual length of stay that occurred during the episode is less than

the geometric mean, the normal MS–DRG payment amount is allocated to the episode based on the number of inpatient days that fall within the episode.

(iv) If the full amount is not allocated to the episode, any remainder amount is allocated to the post-episode spending calculation (defined in § 510.2).

Subpart E—Quality Measures, Beneficiary Protections, and Compliance Enforcement

§ 510.400 Quality measures and reporting.

(a) *Reporting of quality measures.* The following quality measures are used for public reporting, for determining whether a participant hospital is eligible for reconciliation payments under § 510.305(g), and whether a participant hospital is eligible for quality incentive payments under § 510.315(f) in the performance year or performance year subset:

(1) Hospital-level risk-standardized complication rate following elective primary total hip arthroplasty and/or total knee arthroplasty.

(2) Hospital Consumer Assessment of Healthcare Providers and Systems Survey.

(b) *Requirements for successful voluntary data submission of patient-reported outcomes and limited risk variable data.* To be eligible to receive the additional points added to the composite quality score for successful voluntary data submission of patient-reported outcomes and limited risk variable data, as described in § 510.315(b)(4), participant hospitals must submit the THA/TKA patient-reported outcome and limited risk variable data requested by CMS related to the pre- and post-operative periods for elective primary total hip and/or total knee arthroplasty procedures. The data must be submitted within 60 days of the end of the most recent performance period and be accompanied by the patient-reported outcomes and limited risk variable data (eleven elements finalized) as outlined in § 510.315(b)(4).

(1) For each eligible procedure all eleven risk variable data elements are required to be submitted. The eleven risk variables are as follows:

(i) Date of birth.

(ii) Race.

(iii) Ethnicity.

(iv) Date of admission to anchor hospitalization.

(v) Date of eligible THA/TKA procedure.

(vi) Medicare Health Insurance Claim Number.

(vii) Body mass index.

(viii) Use of chronic (≥90 day) narcotics.

(ix) Total painful joint count.

(x) Quantified spinal pain.

(xi) Single Item Health Literacy Screening (SILS2) questionnaire.

(2) Hospitals must also submit the amount of requested THA/TKA patient-reported outcomes data required for each performance year or performance year subset of the model in order to be considered successful in submitting voluntary data.

(i) The amount of requested THA/TKA patient-reported outcomes data to submit, in order to be considered successful will increase each subsequent year of the model over the first 5 years of the model (with the exception of performance year subset 5.2, for which CMS will request the same amount of THA/TKA patient-reported outcomes data as performance year subset 5.1, updated to reflect the timeframe applicable to performance year subset 5.2).

(ii) A phase-in approach that determines the amount of requested THA/TKA patient-reported outcomes data to submit over performance years 1 through 4 and performance year subset 5.1 (with the exception of performance year subset 5.2, for which CMS will request the same amount of THA/TKA patient-reported outcomes as performance year subset 5.1, updated to reflect the timeframe applicable to performance year subset 5.2) of the model will be applied so that in year 1 successful submission of data would mean CMS received all requested THA/TKA patient-reported outcomes and limited risk variable data on both of the following:

(A) Greater than or equal to 50 percent of eligible procedures or greater than or equal to 50 eligible patients during the data collection period.

(B) Submission of requested THA/TKA PRO and limited risk variable

data is completed within 60 days of the most recent performance period.

(3) For years 1 through 5 of the model an increasing amount of data is requested by CMS for each performance period as follows:

(i) Year 1 (2016). Submit pre-operative data on primary elective THA/TKA procedures for ≥50% or ≥50 eligible procedures performed between July 1, 2016 and August 31, 2016, unless CMS requests a more limited data set, in which case, submit all requested data elements.

(ii) Year 2 (2017). Submit—

(A) Post-operative data on primary elective THA/TKA procedures for ≥50% or ≥50 eligible procedures performed between July 1, 2016 through August 31, 2016; and

(B) Pre-operative data on primary elective THA/TKA procedures for ≥60% or ≥75 procedures performed between September 1, 2016 through June 30, 2017, unless CMS requests a more limited data set, in which case, submit all requested data elements.

(iii) Year 3 (2018). Submit—

(A) POST-operative data on primary elective THA/TKA procedures for ≥60% or ≥75 procedures performed between September 1, 2016 and June 30, 2017; and

(B) Pre-operative data on primary elective THA/TKA procedures for ≥70% or ≥100 procedures performed between July 1, 2017 and June 30, 2018, unless CMS requests a more limited data set, in which case, submit all requested data elements.

(iv) Year 4 (2019). Submit—

(A) Post-operative data on primary elective THA/TKA procedures for ≥70% or ≥100 procedures performed between July 1, 2017 and June 30, 2018; and

(B) Pre-operative data on primary elective THA/TKA procedures for ≥80% or ≥200 procedures performed between July 1, 2018 and June 30, 2019, unless CMS requests a more limited data set, in which case, submit all requested data elements.

(v) Year 5 (subset 5.1, January 1, 2020–December 31, 2020). Submit—

(A) Post-operative data on primary elective THA/TKA procedures for ≥80% or ≥200 procedures performed between July 1, 2018 and June 30, 2019 and

(B) Pre-operative data on primary elective THA/TKA procedures for ≥80% or ≥200 procedures performed between July 1, 2019 and June 30, 2020, unless CMS requests a more limited data set, in which case, submit all requested data elements.

(vi) Year 5 (subset 5.2, January 1, 2021–September 30, 2021). Submit—

(A) Post-operative data on primary elective THA/TKA procedures for ≥80% or ≥200 procedures performed between July 1, 2019 and June 30, 2020; and

(B) Pre-operative data on primary elective THA/TKA procedures for ≥80% or ≥200 procedures performed between July 1, 2020 and June 30, 2021, unless CMS requests a more limited data set, in which case, submit all requested data elements.

(4) For years 6 through 8 of the model the following data are requested by CMS for each performance period as follows:

(i) Year 6 (October 1, 2021 to December 31, 2022). Submit—

(A) Post-operative data on primary elective THA/TKA procedures for ≥80% or ≥200 procedures performed between July 1, 2019 and June 30, 2020; and

(B) Pre-operative data on primary elective THA/TKA procedures for ≥80% or ≥300 procedures performed between July 1, 2021 and June 30, 2022.

(ii) Year 7 (2023). Submit—

(A) Post-operative data on primary elective THA/TKA procedures for ≥80% or ≥300 procedures performed between July 1, 2021 and June 30, 2022; and

(B) Pre-operative data on primary elective THA/TKA procedures for ≥85% or ≥400 procedures performed between July 1, 2022 and June 30, 2023.

(iii) Year 8 (2024). Submit—

(A) Post-operative data on primary elective THA/TKA procedures for ≥85% or ≥400 procedures performed between July 1, 2022 and June 30, 2023; and

(B) Pre-operative data on primary elective THA/TKA procedures for ≥90% or ≥500 procedures performed between July 1, 2023 and June 30, 2024.

(c) *Public reporting.* CMS—

(1) Makes the quality measurement results calculated for the complication and patient survey quality measures described in paragraph (a) of this section for each participant hospital in each performance year publicly available on the CMS Web site in a form and manner as determined by CMS;

(2) Shares each participant hospital's quality metrics with the hospital prior to display on the Web site; and

(3) Does not publicly report the voluntary patient-reported outcomes and limited risk variable data during this model, but indicates whether a hospital has successfully submitted such data in accordance with §510.400(b).

[80 FR 73540, Nov. 24, 2015, as amended at 82 FR 615, Jan. 3, 2017; 85 FR 71201, Nov. 6, 2020; 86 FR 23574, May 3, 2021; 86 FR 36229, July 9, 2021]

§510.405 Beneficiary choice and beneficiary notification.

(a) *Beneficiary choice.* The CJR model does not restrict Medicare beneficiaries' ability to choose any Medicare enrolled provider or supplier, or any physician or practitioner who has opted out of Medicare.

(1) As part of discharge planning and referral, participant hospitals 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 CJR beneficiaries for whom home health care, SNF, IRF, or LTCH services are medically necessary.

(ii) Participant hospitals must specify on the list those post-acute care providers on the list with whom they have a sharing arrangement.

(iii) Participant hospitals may recommend preferred providers and suppliers, consistent with applicable statutes and regulations.

(iv) Participant hospitals may not limit beneficiary choice to any list of providers or suppliers in any manner other than that permitted under applicable statutes and regulations.

(v) Participant hospitals must take into account patient and family preferences when they are expressed.

(2) Participant hospitals may not charge any CJR collaborator a fee to be included on any list of preferred providers or suppliers, nor may the participant hospital accept such payments.

(b) *Required beneficiary notification*—(1) *Participant hospital beneficiary notification*—(i) *Notification to beneficiaries.* Each participant hospital must provide written notification to any Medicare beneficiary that meets the criteria in §510.205 of his or her inclusion in the CJR model.

(ii) *Timing of notification.* Prior to discharge from the anchor hospitalization, or prior to discharge from the anchor procedure, as applicable, the participant hospital must provide the CJR beneficiary with a participant hospital beneficiary notification as described in paragraph (b)(1)(iv) of this section.

(iii) *List of beneficaries receiving a notification.* The participant hospital must be able to generate a list of all beneficiaries receiving 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 the model 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, and how they can share access to their Blue Button® electronic health information with caregivers.

(D) A statement that all existing Medicare beneficiary protections continue to be available to the beneficiary. These include the ability to report concerns of substandard care to Quality Improvement Organizations or the 1–800–MEDICARE helpline.

(E) A list of the providers, suppliers, and ACOs with whom the CJR participant hospital has a sharing arrangement. This requirement may be fulfilled by the participant hospital including in the detailed notification a Web address where beneficiaries may access the list.

(2) *CJR collaborator notice.* A participant hospital must require every CJR collaborator to provide written notice to applicable CJR beneficiaries of the structure of the CJR model and the existence of its sharing arrangement with the participant hospital.

(i) With the exception of ACOs, PGPs, NPPGPs, and TGPs, a CJR participant hospital must require every CJR collaborator that furnishes an item or service to a CJR beneficiary during a CJR episode to provide written notice to the beneficiary of the structure of the model and the existence of the individual's or entity's sharing arrangement. The notice must be provided no later than the time at which the beneficiary first receives an item or service from the CJR collaborator during a CJR 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. The CJR collaborator must be able to generate 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 participant hospital must require every PGP, NPPGP, or TGP that is a CJR collaborator where a member of the PGP, member of the NPPGP, or member of the TGP furnishes an item or service to a CJR beneficiary during a CJR episode to provide written notice to the beneficiary of the structure of the model and the existence of the entity's sharing arrangement. 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. 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. The PGP, NPPGP, or TGP must be able to generate 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 participant hospital must require every ACO that is a CJR collaborator where an ACO participant or ACO provider/supplier furnishes an item or service to a CJR beneficiary during a CJR episode to provide written notice to the beneficiary of the structure of the model and the existence of the entity's sharing arrangement. 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. 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. The ACO must be able to generate 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 participant hospital 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 participant hospital 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 participant hospital must notify the beneficiary that the service would not be covered by Medicare.

(ii) If the participant hospital is discharging a beneficiary to a SNF prior to the occurrence of a 3-day 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 § 510.610, the participant hospital 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 §510.110.

[80 FR 73540, Nov. 24, 2015, as amended at 82 FR 616, Jan. 3, 2017; 86 FR 23574, May 3, 2021]

§510.410 Compliance enforcement.

(a) *General.* Participant hospitals must comply with all of the requirements outlined in this part. Except as specifically noted in this part, the regulations under this part must not be construed to affect the payment, coverage, program integrity, or other requirements (such as those in parts 412 and 482 of this chapter) that apply to providers and suppliers under this chapter.

(b) *Failure to comply.* (1) CMS may take one or more of the remedial actions set forth in paragraph (b)(2) of this section if a participant hospital or its related CJR collaborators, collaboration agents, or downstream collaboration agents—

(i) Fails to comply with any requirements of this part or is identified as noncompliant through monitoring by HHS (including CMS and OIG) of the CJR model, including but not limited to the following:

(A) Avoiding potentially high cost patients.

(B) Targeting potentially low cost patients.

(C) Failing to provide medically appropriate services or systematically engaging in the over or under delivery of appropriate care.

(D) Failing to provide beneficiaries with complete and accurate information, including required notices.

(E) Failing to allow beneficiary choice of medically necessary options, including non-surgical options.

(F) Failing to follow the requirements related to sharing arrangements.

(G) Failing to participate in CJR model-related evaluation activities conducted by CMS or its contractors or both.

(ii) Has signed a sharing arrangement, distribution arrangement, or downstream distribution arrangement that is noncompliant with the requirements of this part.

(iii) Takes any action that threatens the health or safety of patients;

(iv) Avoids at-risk Medicare beneficiaries, as this term is defined in §425.20;

(v) Avoids patients on the basis of payer status;

(vi) Is subject to sanctions or final actions of an accrediting organization or federal, state, or local government agency that could lead to the inability to comply with the requirements and provisions of this part;

(vii) Takes any action that CMS determines for program integrity reasons is not in the best interests of the CJR model, or fails to take any action that CMS determines for program integrity reasons should have been taken to further the best interests of the CJR model;

(viii) Is subject to action by HHS (including OIG and CMS) or the Department of Justice to redress an allegation of fraud or significant misconduct, including intervening in a False Claims Act qui tam matter, issuing a pre-demand or demand letter under a civil sanction authority, or similar actions; or

(ix) Is subject to action involving violations of the physician self-referral law, civil monetary penalties law, federal anti-kickback statute, antitrust laws, or any other applicable Medicare laws, rules, or regulations that are relevant to the CJR model.

(2) Remedial actions include the following:

(i) Issuing a warning letter to the participant hospital.

(ii) Requiring the participant hospital to develop a corrective action plan, commonly referred to as a CAP.

(iii) Reducing or eliminating a participant hospital's reconciliation payment.

(iv) Requiring a participant hospital to terminate a sharing arrangement with a CJR collaborator and prohibiting further engagement in sharing arrangements with the participant hospital by that CJR collaborator.

(v) Terminating the participant hospital's participation in the CJR model. Where a participant is terminated from

the CJR model, the participant hospital will remain liable for all negative NPRA generated from episodes of care that ended prior to termination.

(3) CMS may add a 25 percent penalty to a repayment amount on the participant hospital's reconciliation report if all of the following conditions are met:

(i) CMS has required a corrective action plan from a participant hospital;

(ii) The participant hospital owes a repayment amount to CMS; and

(iii) The participant hospital fails to timely comply with the corrective action plan or is noncompliant with the CJR model's requirements.

[80 FR 73540, Nov. 24, 2015, as amended at 82 FR 617, Jan. 3, 2017; 82 FR 57104, Dec. 1, 2017]

Subpart F—Financial Arrangements and Beneficiary Incentives

§ 510.500 Sharing arrangements under the CJR model.

(a) *General.* (1) A participant hospital may enter into a sharing arrangement with a CJR collaborator to make a gainsharing payment, or to receive an alignment payment, or both. A participant hospital must not make a gainsharing payment or receive an alignment payment except in accordance with a sharing arrangement.

(2) A sharing arrangement must comply with the provisions of this section and all other applicable laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements.

(3) Participant hospitals must develop, maintain, and use a set of written policies for selecting individuals and entities to be CJR collaborators. These policies must contain criteria related to, and inclusive of, the quality of care delivered by the potential CJR collaborator. 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 participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent. A selection criterion that considers whether a potential CJR collaborator has performed a reasonable minimum number of services that would qualify as CJR activities 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 CJR beneficiaries.

(4) If a participant hospital enters into a sharing arrangement, its compliance program must include oversight of sharing arrangements and compliance with the applicable requirements of the CJR model.

(b) *Requirements.* (1) A sharing arrangement must be in writing and signed by the parties, and entered into before care is furnished to CJR 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 CJR 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 CJR collaborator to have or be covered by a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of the CJR model that apply to its role as a CJR 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 participant hospital must have responsibility for overseeing the participant hospital's participation in the CJR model, its arrangements with CJR collaborators, its payment of gainsharing payments, its receipt of alignment payments, and its use of beneficiary incentives in the CJR model.

(7) The written agreement memorializing a sharing arrangement must specify the following:

(i) The purpose and scope of the sharing arrangement.

(ii) The obligations of the parties, including specified CJR activities and other services to be performed by the parties under the sharing arrangement.

(iii) The date of the sharing arrangement.

(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 payment.

(D) Methodology and accounting formula for determining the amount of a gainsharing payment or alignment payment.

(8) The sharing arrangement must not—

(i) Induce the participant hospital, CJR collaborator, or any employees, contractors, or subcontractors of the participant hospital or CJR collaborator to reduce or limit medically necessary services to any Medicare beneficiary; or

(ii) Restrict the ability of a CJR 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 payments, 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 CJR collaborator must meet quality of care criteria for the performance year for which the participant hospital 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 participant hospital and directly related to the CJR episode.

(ii) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a CJR collaborator other than ACO, PGP, NPPGP, or TGP must have directly furnished a billable item or service to a CJR beneficiary during a CJR episode that occurred in the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount.

(iii) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a CJR 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 CJR beneficiary during a CJR episode that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount.

(B) The PGP, NPPGP, or TGP must have contributed to CJR activities and been clinically involved in the care of CJR beneficiaries during the same performance year for which the CJR participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount. For example, a PGP, NPPGP, or TGP might have been clinically involved in the care of CJR beneficiaries by—

(*1*) Providing care coordination services to beneficiaries during and/or after inpatient admission;

(*2*) Engaging with a participant hospital in care redesign strategies, and actually performing a role in implementing such strategies, that are designed to improve the quality of care for CJR episodes and reduce CJR episode spending; or

(*3*) In coordination with other providers and suppliers (such as PGP members, NPPGP members, or TGP members; the participant hospital; and post-acute care providers), implementing strategies designed to address and manage the comorbidities of CJR beneficiaries.

(iv) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a CJR 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 CJR beneficiary during a CJR episode that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount; and

(B) The ACO must have contributed to CJR activities and been clinically involved in the care of CJR beneficiaries during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed the repayment amount. For example, an ACO might be have been clinically involved in the care of CJR beneficiaries by—

(*1*) Providing care coordination services to CJR beneficiaries during and/or after inpatient admission;

(*2*) Engaging with a participant hospital in care redesign strategies, and actually performing a role in implementing such strategies, that are designed to improve the quality of care and reduce spending for CJR episodes; or

(*3*) In coordination with providers and suppliers (such as ACO participants, ACO providers/suppliers, the participant hospital, and post-acute care providers), implementing strategies designed to address and manage the comorbidities of CJR beneficiaries.

(3)(i) The methodology for accruing, calculating and verifying internal cost savings must be transparent, measurable, and verifiable in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book).

(ii) The methodology used to calculate internal cost savings must reflect the actual, internal cost savings achieved by the participant hospital through the documented implementation of CJR activities identified by the participant hospital and must exclude—

(A) Any savings realized by any individual or entity that is not the participant hospital; and

(B) ''Paper'' savings from accounting conventions or past investment in fixed costs.

(4) The total amount of a gainsharing payment for a performance year paid to a CJR collaborator must not exceed the following:

(i) For episodes beginning on or after April 1, 2016 and ending on or before September 30, 2021, in the case of a CJR collaborator who is a physician or non-physician practitioner, 50 percent of the Medicare-approved amounts under the PFS for items and services furnished by that physician or non-physician practitioner to the participant hospital's CJR beneficiaries during CJR model episodes that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being made.

(ii) For episodes beginning on or after April 1, 2016 and ending on or before September 30, 2021, in the case of a CJR collaborator that is a PGP or NPPGP, 50 percent of the Medicare-approved amounts under the PFS for items and services billed by that PGP or NPPGP and furnished to the participant hospital's CJR beneficiaries by the PGP members or NPPGP members respectively during CJR model episodes that occurred during the same performance year for which the participant hospital

accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being made.

(5) The amount of any gainsharing payments must be determined in accordance with a methodology that is substantially based on quality of care and the provision of CJR activities. The methodology may take into account the amount of such CJR activities provided by a CJR collaborator relative to other CJR collaborators.

(6) For a performance year, the aggregate amount of all gainsharing payments that are derived from a reconciliation payment the CJR participant hospital receives from CMS must not exceed the amount of that reconciliation payment.

(7) 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 participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent.

(8) A participant hospital must not make a gainsharing payment to a CJR collaborator if CMS has notified the participant hospital that such collaborator is subject to any action for noncompliance with this part or the fraud and abuse laws, or for the provision of substandard care to CJR beneficiaries or other integrity problems.

(9) The sharing arrangement must require the participant hospital to recoup any gainsharing payment that contained funds derived from a CMS overpayment on a reconciliation report or was based on the submission of false or fraudulent data.

(10) Alignment payments from a CJR collaborator to a participant hospital 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 reflected in a reconciliation report;

(ii) Loans, advance payments, or payments for referrals or other business; or

(iii) Assessed by a participant hospital if it does not owe a repayment amount.

(11) The participant hospital must not receive any amounts under a sharing arrangement from a CJR collaborator that are not alignment payments.

(12) For a performance year, the aggregate amount of all alignment payments received by the participant hospital must not exceed 50 percent of the participant hospital's repayment amount.

(13) The aggregate amount of all alignment payments from a CJR collaborator to the participant hospital may not be greater than—

(i) With respect to a CJR collaborator other than an ACO, 25 percent of the participant hospital's repayment amount.

(ii) With respect to a CJR collaborator that is an ACO, 50 percent of the participant hospital's repayment amount.

(14) 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 participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent.

(15) All gainsharing payments and any alignment payments must be administered by the participant hospital in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book).

(16) All gainsharing payments and alignment payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(d) *Documentation requirements.* (1) Participant hospitals 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 CJR participant hospital's Web site—

(A) Accurate current and historical lists of all CJR collaborators, including CJR collaborator names and addresses.

(B) Written policies for selecting individuals and entities to be CJR collaborators required by § 510.500(a)(3).

(iii) Maintain and require each CJR 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;

(E) Date and amount of any recoupment of all or a portion of a CJR collaborator's gainsharing payment.

(F) Explanation for each recoupment, such as whether the CJR collaborator received a gainsharing payment that contained funds derived from a CMS overpayment on a reconciliation report, or was based on the submission of false or fraudulent data.

(2) The participant hospital must keep records of all of the following:

(i) Its process for determining and verifying its potential and current CJR 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 payments and internal cost savings.

(v) Its plan to track gainsharing payments and alignment payments.

(3) The participant hospital must retain and provide access to, and must require each CJR collaborator to retain and provide access to, the required documentation in accordance with § 510.110.

[82 FR 617, Jan. 3, 2017, as amended at 86 FR 23575, May 3, 2021]

§ 510.505 Distribution arrangements.

(a) *General.* (1) An ACO, PGP, NPPGP, or TGP that has entered into a sharing arrangement with a participant hospital may distribute all or a portion of any gainsharing payment it receives from the participant hospital 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 date of the agreement, and be entered into before care is furnished to CJR 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 participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR 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 substantially based on quality of care and the provision of CJR activities and that may take into account the amount of such CJR activities provided by a collaboration agent relative to other collaboration agents.

(6) The amount of any distribution payments from a PGP must be determined either in a manner that complies with §411.352(g) of this chapter or in accordance with a methodology that is substantially based on quality of care and the provision of CJR activities and that may take into account the amount of such CJR activities provided by a collaboration agent relative to other collaboration agents.

(7) Except for a distribution payment from a PGP to a PGP member that complies with §411.352(g) of this chapter, a collaboration agent is eligible to receive a distribution payment only if the collaboration agent furnished or billed for an item or service rendered to a CJR beneficiary during a CJR episode that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed.

(8) Except for a distribution payment from a PGP to a PGP member that complies with §411.352(g) of this chapter, the total amount of distribution payments for a performance year paid to a collaboration agent must not exceed the following:

(i) For episodes beginning on or after April 1, 2016 and ending on or before September 30, 2021, in the case of a collaboration agent that is a physician or non-physician practitioner, 50 percent of the total Medicare-approved amounts under the PFS for items and services furnished by the collaboration agent to the participant hospital's CJR beneficiaries during CJR model episodes that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed.

(ii) For episodes beginning on or after April 1, 2016 and ending on or before September 30, 2021, in the case of a collaboration agent that is a PGP or NPPGP, 50 percent of the total Medicare-approved amounts under the PFS for items and services billed by that PGP or NPPGP for items and services furnished by PGP members or NPPGP member respectively to the participant hospital's CJR beneficiaries during CJR model episodes that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed.

(9) With respect to the distribution of any gainsharing payment received by an ACO, PGP, NPPGP, or TGP, the total amount of all distribution payments must not exceed the amount of the gainsharing payment received by the CJR collaborator from the participant hospital.

(10) All distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(11) The collaboration agent must retain the ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

(12) The distribution arrangement must not—

(i) Induce the collaboration agent to reduce or limit medically necessary items and services to any Medicare beneficiary; or

(ii) Reward the provision of items and services that are medically unnecessary.

(13) The CJR collaborator must maintain contemporaneous documentation regarding distribution arrangements in accordance with §510.110, including the following:

(i) The relevant written agreements;

(ii) The date and amount of any distribution payment(s);

(iii) The identity of each collaboration agent that received a distribution payment; and

(iv) A description of the methodology and accounting formula for determining the amount of any distribution payment.

(14) The CJR collaborator may not enter into a distribution arrangement with any individual or entity that has a sharing arrangement with the same participant hospital.

(15) The CJR collaborator must retain and provide access to, and must require collaboration agents to retain

and provide access to, the required documentation in accordance with § 510.110.

[82 FR 620, Jan. 3, 2017, as amended at 86 FR 23575, May 3, 2021]

§ 510.506 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 CJR collaborator that is an ACO may distribute all or a portion of any distribution payment it receives from the CJR collaborator only in accordance with 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 date of the agreement, and be entered into before care is furnished to CJR 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 participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR 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 substantially based on quality of care and the provision CJR activities and that may take into account the amount of such CJR 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 either in a manner that complies with § 411.352(g) of this chapter or in accordance with a methodology that is substantially based on quality of care and the provision CJR activities and that may take into account the amount of such CJR activities provided by a downstream collaboration agent relative to other downstream collaboration agents.

(7) Except for a downstream distribution payment from a PGP to a PGP member that complies with § 411.352(g) of this chapter, a downstream collaboration agent is eligible to receive a downstream distribution payment only if the downstream collaboration agent furnished an item or service by the downstream collaboration agent to a CJR beneficiary during a CJR episode that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment 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) Except for a downstream distribution payment from a PGP to a PGP member that complies with § 411.352(g) of this chapter, for episodes beginning on or after April 1, 2016 and ending on or before September 30, 2021 the total amount of downstream distribution payments for a performance year paid to a downstream collaboration agent who is a physician or non-physician practitioner and is either a member of a PGP or a member of an NPPGP must not exceed 50 percent of the total Medicare-approved amounts under the PFS for items and services furnished by the downstream collaboration agent to the participant hospital's CJR beneficiaries during a CJR model episode that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the distribution payment being distributed.

(9) 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.

(10) All downstream distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(11) The downstream collaboration agent must retain his or her ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

(12) 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.

(13) The PGP, NPPGP, or TGP must maintain contemporaneous documentation regarding downstream distribution arrangements in accordance with §510.110, 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.

(14) 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 participant hospital.

(ii) A distribution arrangement with the ACO that the PGP, NPPGP, or TGP is a participant in.

(15) 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 §510.110.

[82 FR 621, Jan. 3, 2017, as amended at 86 FR 23575, May 3, 2021]

§510.510 Enforcement authority.

(a) *OIG authority.* OIG authority is not limited or restricted by the provisions of the CJR model, including the authority to audit, evaluate, investigate, or inspect the participant hospital, CJR collaborators, or any other person or entity or their records, data, or information, without limitation.

(b) *Other authorities.* None of the provisions of the CJR model limits or restricts the authority of any other government agency permitted by law to audit, evaluate, investigate, or inspect the participant hospital, CJR collaborators, or any other person or entity or their records, data, or information, without limitation.

§510.515 Beneficiary incentives under the CJR model.

(a) *General.* Participant hospitals may choose to provide in-kind patient engagement incentives to beneficiaries in a CJR episode, subject to the following conditions:

(1) The incentive must be provided directly by the participant hospital or by an agent of the hospital under the hospital's direction and control to the beneficiary during a CJR episode of care.

(2) The item or service provided must be reasonably connected to medical care provided to a beneficiary during a CJR episode of care.

(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 beneficiary in a CJR episode by engaging the 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 CJR episode of care.

(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 beneficiary may be made aware of the availability of the items or services at the time the beneficiary could reasonably benefit from them.

(7) The cost of the items or services must not be shifted to another federal

health care program, as defined at section 1128B(f) of the Act.

(b) *Technology provided to a CJR beneficiary.* Beneficiary engagement incentives involving technology are subject to the following additional conditions:

(1) Items or services involving technology provided to a beneficiary may not exceed $1,000 in retail value for any one beneficiary in any one CJR episode.

(2) Items or services involving technology provided to a beneficiary must be the minimum necessary to advance a clinical goal, as listed in paragraph (c) of this section, for a beneficiary in a CJR episode.

(3) Items of technology exceeding $100 in retail value must—

(i) Remain the property of the CJR participant; and

(ii) Be retrieved from the beneficiary at the end of the CJR episode. The participant hospital must document all retrieval attempts, including the ultimate date of retrieval. Documented, diligent, good faith attempts to retrieve items of technology will be deemed to meet the retrieval requirement.

(c) *Clinical goals of the CJR model.* The following are the clinical goals of the CJR model, which may be advanced through beneficiary incentives:

(1) Beneficiary adherence to drug regimens.

(2) Beneficiary adherence to a care plan.

(3) Reduction of readmissions and complications resulting from LEJR procedures.

(4) Management of chronic diseases and conditions that may be affected by the LEJR procedure.

(d) *Documentation of beneficiary incentives.* (1) Participant hospitals 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 and must include at least the following:

(i) The date the incentive is provided.

(ii) The identity of the beneficiary to whom the item or service was provided.

(3) The documentation regarding items of technology exceeding $100 in retail value must also include contemporaneous documentation of any attempt to retrieve technology at the end of a CJR episode as described in paragraph (b)(3) of this section.

(4) The CJR participant hospital must retain and provide access to the required documentation in accordance with § 510.110.

[80 FR 73540, Nov. 24, 2015, as amended at 82 FR 621, Jan. 3, 2017]

Subpart G—Waivers

§ 510.600 Waiver of direct supervision requirement for certain post-discharge home visits.

(a) *General.* CMS waives the requirement in § 410.26(b)(5) of this chapter that services and supplies furnished incident to a physician's service must be furnished under the direct supervision of the physician (or other practitioner) to permit home visits as specified in this section. The services furnished under this waiver are not considered to be ''hospital services,'' even when furnished by the clinical staff of the hospital.

(b) *General supervision of qualified personnel.* The waiver of the direct supervision requirement in § 410.26(b)(5) of this chapter applies only in the following circumstances:

(1) The home visit is furnished during the episode to a beneficiary who has been discharged from an anchor hospitalization or anchor procedure.

(2) The home visit is furnished at the beneficiary's home or place of residence.

(3) The beneficiary does not qualify for home health services under sections 1835(a) and 1814(a) of the Act at the time of any such home visit.

(4) The visit is furnished by clinical staff under the general supervision of a physician or non-physician practitioner. Clinical staff are individuals who work under the supervision of a physician or other qualified health care professional, and who are allowed by law, regulation, and facility policy to perform or assist in the performance of a specific professional service, but do not individually report that professional service.

(5) No more than 9 visits are furnished to the beneficiary during the episode.

(c) *Payment.* Up to 9 post-discharge home visits per CJR episode may be billed under Part B by the physician or nonphysician practitioner or by the participant hospital to which the supervising physician has reassigned his or her billing rights.

(d) *Other requirements.* All other Medicare rules for coverage and payment of services incident to a physician's service continue to apply.

[80 FR 73540, Nov. 24, 2015, as amended at 86 FR 23575, May 3, 2021]

§ 510.605 Waiver of certain telehealth requirements.

(a) *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 the CJR model, but only for services that—

(1) May be furnished via telehealth under existing requirements; and

(2) Are included in the episode in accordance with § 510.200(b).

(b) *Waiver of the originating site requirements.* Except for the originating site requirements for a face-to-face encounter for home health certification, CMS waives the originating site requirements under section 1834(m)(4)(C)(ii)(I) through (VIII) of the Act for episodes being tested in the CJR model to permit a telehealth visit to originate in the beneficiary's home or place of residence, but only for services that—

(1) May be furnished via telehealth under existing requirements; and

(2) Are included in the CJR episode in accordance with § 510.200(b).

(c) *Waiver of selected payment provisions.* (1) CMS waives the payment requirements under section 1834(m)(2)(A) 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.

(2) 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 this model.

(d) *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.

[80 FR 73540, Nov. 24, 2015, as amended at 82 FR 57104, Dec. 1, 2017]

§ 510.610 Waiver of SNF 3-day rule.

(a) *Waiver of the SNF 3-day rule*—(1) *Performance year*—(i) *Performance years 2 through 5.* For episodes being tested in performance years 2 through 5 of the CJR model, CMS waives the SNF 3-day rule for coverage of a SNF stay for a beneficiary who is a CJR beneficiary on the date of discharge from the anchor hospitalization, but only if the SNF is identified on the applicable calendar quarter list of qualified SNFs at the time of the CJR beneficiary's admission to the SNF.

(ii) *Performance years 6 through 8.* (A) For episodes being tested in performance years 6 through 8 of the CJR model, 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 CJR beneficiary on the date of discharge from the anchor hospitalization, but only if the SNF is identified on the applicable calendar quarter list of qualified SNFs at the time of the CJR beneficiary's admission to the SNF.

(B) For episodes being tested in performance years 6 through 8 of the CJR model, 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 CJR beneficiary on the date of service of the anchor procedure, but only if the SNF is identified on the applicable calendar quarter list of qualified SNFs at the time of the CJR beneficiary's admission to the SNF.

(2) *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.

(3) *Posting of qualified SNFs.* CMS posts to the CMS website the list of qualified SNFs in advance of the calendar quarter.

(b) *Financial liability for non-covered SNF services.* If CMS determines that the waiver requirements specified in paragraph (a) of this section were not met, the following apply:

(1) CMS makes no payment to a SNF for SNF services if the SNF admits a CJR beneficiary who has not had a qualifying inpatient stay or anchor procedure.

(2) In the event that CMS makes no payment for SNF services furnished by a SNF as a result of paragraph (b)(1) of this section, the beneficiary protections specified in paragraph (b)(3) of this section apply, unless the participant hospital has provided the beneficiary with a discharge planning notice in accordance with § 510.405(b)(3).

(3) If the participant hospital does not provide the beneficiary with a discharge planning notice in accordance with § 510.405(b)(3)—

(i) The SNF must not charge the beneficiary for the expenses incurred for such services;

(ii) The SNF must return to the beneficiary any monies collected for such services; and

(iii) The participant hospital is financially liable for the expenses incurred for such services.

(4) If the participant hospital provided a discharge planning notice to the beneficiary in accordance with § 510.405(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.

[82 FR 622, Jan. 3, 2017, as amended at 86 FR 23575, May 3, 2021]

§ 510.615 Waiver of certain post-operative billing restrictions.

(a) *Waiver to permit certain services to be billed separately during the 90-day post-operative global surgical period.* CMS waives the billing requirements for global surgeries to allow the separate billing of certain post-discharge home visits described under § 510.600, including those related to recovery from the surgery, as described in paragraph (b) of this section, for episodes being tested in the CJR model.

(b) *Services to which the waiver applies.* Up to 9 post-discharge home visits, including those related to recovery from the surgery, per CJR episode may be billed separately under Part B by the physician or nonphysician practitioner, or by the participant hospital to which the physician or nonphysician practitioner has reassigned his or her billing rights.

(c) *Other requirements.* All other Medicare rules for global surgery billing during the 90-day post-operative period continue to apply.

§ 510.620 Waiver of deductible and coinsurance that otherwise apply to reconciliation payments or repayments.

(a) *Waiver of deductible and coinsurance.* CMS waives the requirements of sections 1813 and 1833(a) of the Act for Medicare Part A and Part B payment systems only to the extent necessary to make reconciliation payments or receive repayments based on the NPRA that reflect the episode payment methodology under the final payment model for CJR participant hospitals.

(b) *Reconciliation payments or repayments.* Reconciliation payments or repayments do not affect the beneficiary cost-sharing amounts for the Part A and Part B services provided under the CJR model.

[80 FR 73540, Nov. 24, 2015, as amended at 82 FR 622, Jan. 3, 2017]

Subparts H–J [Reserved]

Subpart K—Model Termination

§ 510.900 Termination of the CJR model.

CMS may terminate the CJR model for reasons including but not limited to the following:

(a) CMS determines that it no longer has the funds to support the CJR model.

(b) CMS terminates the model in accordance with section 1115A(b)(3)(B) of the Act. As provided by section 1115A(d)(2) of the Act, termination of

the model is not subject to administrative or judicial review.

PART 512—RADIATION ONCOLOGY MODEL AND END STAGE RENAL DISEASE TREATMENT CHOICES MODEL

Subpart A—General Provisions Related to Innovation Center Models

Subpart B—Radiation Oncology Model

Subpart C—ESRD Treatment Choices Model

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