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and signing an individualized treatment plan for CR and ICR services to be furnished under the direction of—

(1) A physician, as defined in section 1861(r)(1) of the Act; or

(2) A qualified nonphysician practitioner, as defined by CMS.

(c) *Other definitions and requirements.* All other definitions and requirements in § 410.49 of this chapter related to a physician or supervising physician continue to apply.

Subpart H—CR Incentive Payment Model for EPM and Medicare Fee-for-Service Participants

§ 512.700 Basis and scope.

(a) *Basis.* This subpart implements the cardiac rehabilitation (CR) and intensive cardiac rehabilitation (ICR) incentive payment model under section 1115A of the Act.

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

(1) The participants in the CR incentive payment model.

(2) The CR/ICR services that count toward CR incentive payments.

(3) The methodology for determining CR incentive payments.

(4) Provisions for FFS-CR participants that are not EPM participants.

§ 512.703 CR incentive payment model participants.

(a) *Selection of CR MSAs.* The MSAs eligible for selection for AMI and CABG models were classified into one of seven groups based on their historic utilization of CR/ICR services. Within each group, EPM-CR and FFS-CR MSAs were randomly selected. The number of EPM-CRs selected within each group are distributed proportionately between the groups based on the assignment of the 98 EPM MSAs. The same number of FFS-MSAs were then drawn from each group.

(b) *Hospitals eligible for CR incentive payments.* (1) Hospitals that are AMI and CABG model participants located in the EPM-CR MSAs.

(2) *FFS-CR participants.* Hospitals located in the FFS-CR MSAs that would meet all requirements in § 512.100(b) to be an AMI or CABG model participant if the hospital were located in an MSA selected for the AMI and CABG models.

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§ 512.705 CR/ICR services that count towards CR incentive payments.

(a) *Identification of CR/ICR services.* CR/ICR services are identified by the HCPCS codes for CR/ICR services included in the CMS change request that implements the National Coverage Determination in the CR performance year.

(b) *CR participant eligibility for CR incentive payment.* (1) For EPM-CR participants, CR/ICR services paid by Medicare under the OPPS or to any supplier reporting place of service code 11 on the PFS claim for AMI and CABG model beneficiaries during AMI and CABG model episodes result in eligibility for CR incentive payments.

(2) For FFS-CR participants, CR/ICR services paid by Medicare under the OPPS or to any supplier reporting place of service code 11 on the PFS claim for beneficiaries during AMI care periods and CABG care periods that would meet the requirements to be AMI and CABG model episodes in accordance with all provisions in subpart B if the FFS-CR participant were an EPM participant result in eligibility for CR incentive payments.

(c) *Overlap between AMI care periods and CABG care periods with AMI and CABG model episodes.* (1) An AMI care period or CABG care period does not begin if the beneficiary is in an AMI or CABG model episode when the AMI care period or CABG care period would otherwise begin.

(2) An AMI care period or CABG care period is canceled if at any time during the AMI care period or CABG care period the beneficiary initiates an AMI or CABG model episode.

(d) *CR incentive payment time period.* All AMI and CABG model episodes and AMI care periods and CABG care periods begin on or after July 1, 2017 and end on or before December 31, 2021.

§ 512.710 Determination of CR incentive payments.

(a) *General.* CMS provides a CR incentive payment for each CR performance year to each EPM-CR participant and FFS-CR participant based on CR/ICR services paid by Medicare under the OPPS or to any supplier reporting place of service code 11 on the PFS claim for beneficiaries in AMI and

CABG model episodes or AMI and CABG care periods, respectively. CMS makes CR incentive payments from the Medicare Part B Trust Fund to CR participants, and also submits beneficiary-specific CR amounts to the CMS Master Database Management System. The initial level of the per-service CR incentive amount is \$25 per CR/ICR service for each of up to 11 CR/ICR services paid for by Medicare. For those CR/ICR services in an AMI or CABG model episode or AMI care period or CABG care period that exceed 11, the per-service CR incentive amount increases to \$175 per CR/ICR service for each additional CR/ICR service paid for by Medicare.

(b) *Determination of CR incentive payment.* At the same time that CMS carries out the determination of NPRA and reconciliation process for an EPM performance year as specified in §512.305 for EPM participants, CMS also determines each CR participant's CR incentive payment for the CR performance year according to the following:

(1) *CR amount when the CR service count is less than 12.* CMS determines the CR amount for a beneficiary in an AMI or CABG model episode or AMI care period or CABG care period with a CR service count less than 12 by multiplying the CR service count by \$25.

(2) *CR amount when the CR service count is 12 or more.* CMS determines the CR amount for a beneficiary in an AMI or CABG model episode or AMI care period or CABG care period with a CR service count of 12 or more as the sum of \$275 (\$25 multiplied by 11 for the first 11 CR/ICR services paid for by Medicare) and \$175 multiplied by the difference between the CR service count and 11.

(3) *CR incentive payment.* CMS sums the CR amounts determined in paragraphs (b)(1) and (2) of this section across the CR participant's beneficiaries in AMI and CABG model episodes or AMI care periods and CABG care periods for a given CR performance year to determine the CR incentive payment for the CR performance year.

(c) *Relation of CR incentive payments to reconciliation and Medicare repayments under EPMs.* CR incentive payments to EPM-CR participants deter-

mined under §512.710(b) are exclusive of reconciliation payments and Medicare repayment amounts determined under §512.305(d).

(d) *Relation of CR incentive payments to sharing arrangements for EPM-CR participants.* CR incentive payments under §512.710(b) are not eligible for and may not be distributed under sharing arrangements specified in §512.500.

(e) *Exclusion of CR incentive payments when updating quality-adjusted target prices for EPM-CR participants.* CR incentive payments under §512.710(b) are excluded when updating quality-adjusted target prices for EPM performance years 3 through 5.

(f) *CR incentive payment report.* At the same time CMS issues the reconciliation report as specified in §512.305(f) to EPM participants, CMS issues each EPM-CR participant and each FFS-CR participant a CR incentive payment report for the CR performance year. Each report contains the following:

(1) The number of AMI and CABG model episodes or AMI care periods and CABG care periods attributed to the CR participant in which Medicare paid for 11 or fewer CR/ICR services for a beneficiary during the CR performance year, if any.

(2) The total number of CR/ICR services Medicare paid for during AMI and CABG model episodes or AMI care periods and CABG care periods identified in paragraph (f)(1) of this section.

(3) The amount of the CR incentive payment attributable to the AMI and CABG model episodes or AMI care periods and CABG care periods identified in paragraph (f)(1) of this section.

(4) The number of AMI and CABG model episodes or AMI care periods and CABG care periods attributed to the CR participant in which Medicare paid for 12 or more CR/ICR services for a beneficiary during the CR performance year, if any.

(5) The total number of CR/ICR services Medicare paid for during AMI and CABG model episodes or AMI care periods and CABG care periods identified in paragraph (f)(4) of this section.

(6) The amount of the CR incentive payment attributable to the AMI and CABG model episodes or AMI care periods and CABG care periods identified in paragraph (f)(4) of this section.

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(7) The total amount of the CR incentive payment.

(g) *Timing of CR incentive payments.* CMS makes CR incentive payments on a retrospective basis subject to the following:

(1) For EPM-CR participants, CMS makes the CR incentive payment, if any, concurrently with EPM reconciliation payments or repayment amounts assessed for a specific EPM and CR performance year, subject to the appeals process for EPM participants in §512.310.

(2) For FFS-CR participants, CMS makes the CR incentive payments, if any, at the same time as for EPM-CR participants, subject to the provisions in §512.720.

PROVISIONS FOR FFS-CR PARTICIPANTS

§512.715 Access to records and retention for FFS-CR participants.

FFS-CR participants and any other individuals or entities providing items or services to a FFS-CR beneficiary 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 CR/ICR service utilization and payments, billings, and the documentation required under §512.740(d)) sufficient to enable the audit, evaluation, inspection, or investigation of the following:

(1) The individual's or entity's compliance with CR incentive payment model requirements.

(2) The obligation to repay any CR incentive payments owed to CMS.

(b) Maintain all such books, contracts, records, documents, and other evidence for a period of 10 years from the last day of the FFS-CR participant's participation in the CR incentive payment 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 FFS-CR participant at least 30 calendar days before the disposition date; or

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(2) There has been a dispute or allegation of fraud or similar fault against the FFS-CR participant or any other individual or entity providing items or services to a FFS-CR beneficiary, 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.

§512.720 Appeals process for FFS-CR participants.

(a) *Notice of calculation error (first level of appeal).* Subject to the limitations on review in subpart H of this part, if a FFS-CR participant wishes to dispute calculations involving a matter related to a CR incentive payment, the FFS-CR participant is required to provide written notice of the calculation error, in a form and manner specified by CMS.

(1) Unless the FFS-CR participant provides such notice, CMS deems final the applicable CR incentive payment report 45 calendar days after the applicable CR incentive payment report is issued and proceeds with the payment as applicable.

(2) If CMS receives a notice of a calculation error within 45 calendar days of the issuance of the applicable CR incentive payment 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 FFS-CR participant.

(3) Only FFS-CR participants may use notice of calculation error process described in this part.

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

(2) The reconsideration request must provide a detailed explanation of the basis for the dispute and include supporting documentation for the FFS-CR participant's assertion that CMS or its representatives did not accurately calculate the CR incentive payment in accordance with subpart H of this part.