(3) If CMS does not receive a request for reconsideration from the FFS-CR participant within 10 calendar days of the issue date of CMS' response to the FFS-CR participant's notice of calculation error, then CMS' response to the calculation error is deemed final and CMS proceeds with the applicable processes, as described in subpart H of this part.

(4) The CMS reconsideration official notifies the FFS-CR participant in writing within 15 calendar days of receiving the FFS-CR participant's review request of the following:

(i) The date, time, and location of the review.
(ii) The issues in dispute.
(iii) The review procedures.
(iv) The procedures (including format and deadlines) for submission of evidence.

(5) The CMS reconsideration official takes all reasonable efforts to schedule the review to occur no later than 30 days after the date of receipt of the notification.

(6) 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 the FFS-CR participant.

(7) The CMS reconsideration official issues a written determination within 30 days of the review. The determination is final and binding.

(8) Only FFS-CR participants may use the dispute resolution process described in this part.

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

(d) Notice of FFS-CR participant termination from the CR incentive payment model. If an FFS-CR participant receives notification that it has been terminated from the CR incentive payment model, it must provide a written request for reconsideration to CMS requesting review of the termination within 10 calendar days of the notice. CMS has 30 days to respond to the FFS-CR participant's request for review. If the FFS-CR participant 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 to expand 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 paragraph (e)(1) or (2) of this section.

§512.725 Data sharing for FFS-CR participants.

(a) General. CMS makes available to FFS-CR participants, through the most appropriate means, data that CMS determines may be useful to FFS-CR participants to do the following:

(1) Determine appropriate ways to increase the coordination of care.
(2) Improve quality.
(3) Enhance efficiencies in the delivery of care.
(4) Otherwise achieve the goals of the model described in this section.

(b) Beneficiary-identifiable data. (1) CMS makes beneficiary-identifiable data available to a FFS-CR participant in accordance with applicable privacy and security laws and only in response
to the FFS-CR participant’s request for such data for a beneficiary who has been furnished a billable service by the FFS-CR participant corresponding to the AMI care period or CABG care period definitions.

(2) The minimum data necessary to achieve the goals of the CR incentive payment test, as determined by CMS, may be provided under this section no less frequently than on a quarterly basis throughout the FFS-CR participant’s participation in the CR incentive payment test.

§ 512.730 Compliance enforcement for FFS-CR participants.

(a) General. FFS-CR participants must comply with all of the requirements outlined in this subpart. Except as specifically noted in this subpart, the regulations under this subpart 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 FFS-CR participant does any of the following:

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

(A) Avoiding potentially high-severity patients.

(B) Targeting potentially low-severity 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.

(ii) Takes any action that threatens the health or safety of patients.

(iii) Avoids at risk Medicare beneficiaries, as this term is defined in §425.20 of this chapter.

(iv) Avoids patients on the basis of payer status.

(v) 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 subpart.

(vi) Takes any action that CMS determines for program integrity reasons is not in the best interests of the CR incentive payment 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 CR incentive payment 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.

(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 CR incentive payment model.

(2) Remedial actions include the following:

(i) Issuing a warning letter to the FFS-CR participant.

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

(iii) Reducing or eliminating the FFS-CR participant’s CR incentive payment.

(iv) Terminating the FFS-CR participant from the CR incentive payment model.

§ 512.735 Enforcement authority for FFS-CR participants.

(a) OIG authority. OIG authority is not limited or restricted by the provisions of the CR incentive payment model, including the authority to audit, evaluate, investigate, or inspect the FFS-CR participant, or any other person or entity or their records, data, or information, without limitation.

(b) Other authorities. None of the provisions of the CR incentive payment model limits or restricts the authority