

## §512.730

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

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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

of any other government agency permitted by law to audit, evaluate, investigate, or inspect the FFS-CR participant or any other person or entity or their records, data, or information, without limitation.

**§ 512.740 Beneficiary engagement incentives for FFS-CR participant use.**

(a) *General.* FFS-CR participants may choose to provide in-kind patient engagement incentives to beneficiaries in an AMI care period or CABG care period, subject to the following conditions:

(1) The incentive must be provided directly by the FFS-CR participant or by an agent of the FFS-CR participant under the FFS-CR participant's direction and control to the FFS-CR beneficiary during an AMI care period or CABG care period.

(2) The item or service provided must be reasonably connected to medical care provided to a FFS-CR beneficiary during an AMI care period or CABG care period.

(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 during an AMI care period or CABG care 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 AMI care period or CABG care period.

(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 items or services must not be advertised or promoted except that a beneficiary may be made aware of the availability of items or services at the time the beneficiary could reasonably benefit from them.

(7) The cost of the item or service must not be shifted to another federal health care program, as defined at section 1128B(f) of the Act.

(b) *Technology provided to an FFS-CR 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 AMI care period or CABG care period.

(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 an AMI care period or CABG care period.

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

(i) Remain the property of the FFS-CR participant; and

(ii) Be retrieved from the beneficiary at the end of the AMI care period or CABG care period. The FFS-CR participant 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 CR incentive payment model.* The following are the clinical goals of the CR incentive payment 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 treatment for AMI or CABG.

(4) Management of chronic diseases and conditions that may be affected by treatment for AMI or CABG.

(d) *Documentation of beneficiary engagement incentives.* (1) FFS-CR participants must maintain documentation of items and services furnished as a beneficiary engagement incentive that exceed \$25 in retail value.

(2) The documentation established contemporaneously with the provision of the items and services 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 must also include contemporaneous documentation of any attempt to retrieve technology at the end of an AMI care period or CABG care period