of care in the calendar year from which the NPRA, as that term is defined in this part, or internal cost savings was generated, either or both of which are the only permitted sources of funds for a gainsharing payment.

(8) The total amount of distribution payments for a calendar year paid to a practice collaboration agent must not exceed 50 percent of the total Medicare approved amounts under the Physician Fee Schedule for services billed by the PGP and furnished by the practice collaboration agent to the participant hospital's CJR beneficiaries during a CJR episode.

(9) With respect to the distribution of any gainsharing payment received by a PGP, the total amount of all distribution payments must not exceed the amount of the gainsharing payment.

(10) All distribution payments must be made through EFT.

(11) The practice collaboration agents must retain their 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 a practice 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 must maintain contemporaneous documentation regarding distribution arrangements in accordance with §510.500(e), including the relevant written agreements, the date and amount of any distribution payment, the identity of each practice collaboration agent who received a distribution payment, and a description of the methodology and accounting formula for determining the amount of any distribution payment.

(14) The PGP may not enter into a distribution arrangement with any member of the PGP that has a collaborator agreement in effect with a participant hospital.

§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 an episode.

(3) The item or service must be a preventive care item or service or an item or service that advances a clinical goal, as listed in paragraph (b) 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) *Goals of the CJR model.* The following are the particular 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 lower extremity joint replacement procedure.

(c) *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 contemporaneous 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 participant hospital must retain the required documentation in accordance with paragraph (e) of this section.

(d) *Technology provided to a beneficiary.* (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 (b) 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 participant hospital; 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.

(e) *Documentation and maintenance of records.* All participant hospitals that provide in-kind patient engagement incentives to beneficiaries in CJR episodes must:

(1) Provide to CMS, the OIG, and the Comptroller General or their designee(s) scheduled and unscheduled access to all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the participant hospital's compliance with CJR requirements for beneficiary incentives.

(2) 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—

(i) CMS determines that there is a special need to retain a particular record or group of records for a longer period and notifies the participant hospital at least 30 calendar days before the normal disposition rate; or

(ii) There has been a dispute or allegation of fraud or similar fault against the participant hospital, in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault.

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.