EPM beneficiaries during EPM episodes that occurred during the same performance year for which the EPM participant 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 § 512.110, 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 an EPM participant; or

(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 § 512.110.

§ 512.520 Enforcement authority under the EPM.

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

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

§ 512.525 Beneficiary engagement incentives under the EPM.

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

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

(2) The item or service provided must be reasonably connected to medical care provided to an EPM beneficiary during an EPM 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 (c) of this section, for a beneficiary in an EPM 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 EPM episode.

(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 an EPM 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 EPM 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 an EPM episode.

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

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

(ii) Be retrieved from the beneficiary at the end of the EPM episode. The EPM 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 EPM*. The following are the clinical goals of the EPM, 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 the EPM clinical condition.

(4) Management of chronic diseases and conditions that may be affected by treatment for the EPM clinical condition.

(d) *Documentation of beneficiary engagement incentives*. (1) EPM participants must maintain documentation of items and services furnished as beneficiary engagement incentives 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 value must also include contemporaneous documentation of any attempt to retrieve technology at the end of an EPM episode as described in paragraph (b)(3) of this section.

(4) The EPM participant must retain and provide access to the required documentation in accordance with §512.110.

Subpart G—Waivers

§512.600 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.

(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