

(iv) A description of the methodology and accounting formula for determining the amount of any distribution payment.

(14) The EPM collaborator may not enter into a distribution arrangement with any individual or entity that has a sharing arrangement with the same EPM participant.

(15) The EPM collaborator must retain and provide access to, and must require collaboration agents to retain and provide access to, the required documentation in accordance with §512.110.

**§512.510 Downstream distribution arrangements under the EPM.**

(a) *General.* (1) An ACO participant that is a PGP, NPPGP, or TGP and that has entered into a distribution arrangement with an EPM collaborator that is an ACO may distribute all or a portion of any distribution payment it receives from the EPM collaborator only in accordance with a downstream distribution arrangement.

(2) All downstream distribution arrangements must comply with the provisions of this section and all applicable laws and regulations, including the fraud and abuse laws.

(b) *Requirements.* (1) All downstream distribution arrangements must be in writing and signed by the parties, contain the date of the agreement, and be entered into before care is furnished to EPM beneficiaries under the downstream distribution arrangement.

(2) Participation in a downstream distribution arrangement must be voluntary and without penalty for non-participation.

(3) The downstream distribution arrangement must require the downstream collaboration agent to comply with all applicable laws and regulations.

(4) The opportunity to make or receive a downstream distribution payment must not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the EPM participant, any EPM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with an EPM participant, EPM

collaborator, collaboration agent, or downstream collaboration agent.

(5) The amount of any downstream distribution payments from an NPPGP to an NPPGP member or from a TGP to a TGP member must be determined in accordance with a methodology that is substantially based on quality of care and the provision EPM activities and that may take into account the amount of such EPM activities provided by a downstream collaboration agent relative to other downstream collaboration agents.

(6) The amount of any downstream distribution payments from a PGP must be determined either in a manner that complies with §411.352(g) of this chapter or in accordance with a methodology that is substantially based on quality of care and the provision EPM activities and that may take into account the amount of such EPM activities provided by a downstream collaboration agent relative to other downstream collaboration agents.

(7) Except for a downstream distribution payment from a PGP to a PGP member that complies with §411.352(g) of this chapter, a downstream collaboration agent is eligible to receive a downstream distribution payment only if the downstream collaboration agent furnished an item or service to an EPM beneficiary during an EPM episode 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 gainsharing payment from which the ACO made the distribution payment to the PGP, NPPGP, or TGP that is an ACO participant.

(8) Except for a downstream distribution payment from a PGP to a PGP member that complies with §411.352(g) of this chapter, the total amount of downstream distribution payments for a performance year paid to a downstream collaboration agent who is a physician or nonphysician practitioner and is either a PGP member or NPPGP member must not exceed 50 percent of the total Medicare-approved amounts under the PFS for items and services furnished by the downstream collaboration agent to the EPM participant's

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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

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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