§ 512.505 Distribution arrangements under the EPM.

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

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

(b) Requirements. (1) All 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 distribution arrangement.

(2) Participation in a distribution arrangement must be voluntary and without penalty for nonparticipation.

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

(4) The opportunity to make or receive a 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.

(15) All gainsharing payments and any alignment payments must be administered by the EPM participant in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book).

(16) All gainsharing payments and alignment payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(d) Documentation requirements. (1) The EPM participant must do all of the following:

(i) Document the sharing arrangement contemporaneously with the establishment of the arrangement.

(ii) Publicly post (and update on at least a quarterly basis) on a Web page on the EPM participant’s Web site:

(A) Accurate current and historical lists of all EPM collaborators, including EPM collaborator names and addresses.

(B) Written policies for selecting individuals and entities to be EPM collaborators required by §512.500(a)(3).

(iii) Maintain and require each EPM collaborator to maintain contemporaneous documentation with respect to the payment or receipt of any gainsharing payment or alignment payment that includes at a minimum all of the following:

(A) Nature of the payment (gainsharing payment or alignment payment).

(B) Identity of the parties making and receiving the payment.

(C) Date of the payment.

(D) Amount of the payment.

(E) Date and amount of any recoupment of all or a portion of an EPM collaborator’s gainsharing payment.

(F) Explanation for each recoupment, such as whether the EPM collaborator received a gainsharing payment that contained funds derived from a CMS overpayment on a reconciliation report, or was based on the submission of false or fraudulent data.

(2) The EPM participant must keep records of the following:

(i) Its process for determining and verifying its potential and current EPM collaborators’ eligibility to participate in Medicare.

(ii) Its plan to track internal cost savings.

(iii) Information on the accounting systems used to track internal cost savings.

(iv) A description of current health information technology, including systems to track reconciliation payments and internal cost savings.

(v) Its plan to track gainsharing payments and alignment payments.

(3) The EPM participant must retain and provide access to, and must require each EPM collaborator to retain and provide access to, the required documentation in accordance with §512.110.
generated by, between or among the
EPM participant, any EPM collabora-
tor, 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 distribution
payments from an ACO, from an
NPPGP to an NPPGP member, or from
a TGP to a TGP member must be de-
termined in accordance with a method-
ology that is substantially based on
quality of care and the provision EPM
activities and that may take into ac-
count the amount of such EPM activi-
ties provided by a collaboration agent
relative to other collaboration agents.

(6) The amount of any distribution
payments from a PGP must be deter-
mined in a manner that com-
mplies with §411.352(g) of this chap-
ter, or in accordance with a methodol-
gy that is substantially based on
quality of care and the provision EPM
activities and that may take into ac-
count the amount of such EPM activi-
ties provided by a collaboration agent
relative to other collaboration agents.

(7) Except for a distribution payment
from a PGP to a PGP member that
complies with §411.352(g) of this chap-
ter, a collaboration agent is eligible to
receive a distribution payment only if
the collaboration agent furnished or
billed for an item or service rendered
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

(8) Except for a distribution payment
from a PGP to a PGP member that
complies with §411.352(g) of this chap-
ter, the total amount of distribution
payments for a performance year paid
to a collaboration agent must not ex-
cede the following:

(i) In the case of a collaboration
agent that is a physician or nonphysi-
cian practitioner, 50 percent of the
total Medicare-approved amounts under the PFS for items and
services furnished by the collaboration agent to
the EPM participant’s EPM benefi-
ciaries during EPM episodes that oc-
curred during the same performance
year for which the EPM participant ac-
crued the internal cost savings or
earned the reconciliation payment that
comprises the gainsharing payment
being distributed.

(ii) In the case of a collaboration
agent that is a PGP or NPPGP, 50 per-
cent of the total Medicare-approved
amounts under the PFS for items and
services billed by that PGP or NPPGP
for items and services furnished by
PGP members or NPPGP members re-
spectively to the EPM participant’s
EPM beneficiaries during EPM epi-
sodes 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

(9) With respect to the distribution of
any gainsharing payment received by
an ACO, PGP, NPPGP, or TGP, the
total amount of all distribution pay-
ments must not exceed the amount of
the gainsharing payment received by
the EPM collaborator from the EPM
participant.

(10) All distribution payments must
be made by check, electronic funds
transfer, or another traceable cash
transaction.

(11) The collaboration agent must re-
tain the ability to make decisions in
the best interests of the patient, in-
cluding the selection of devices, sup-
plies, and treatments.

(12) The distribution arrangement
must not—

(i) Induce the collaboration agent to
reduce or limit medically necessary
items and services to any Medicare
beneficiary; or

(ii) Reward the provision of items
and services that are medically unnec-

(13) The EPM collaborator must
maintain contemporaneous docu-
mentation regarding distribution ar-
rangements in accordance with
§512.110, including the following:

(i) The relevant written agreements.

(ii) The date and amount of any dis-
tribution payment(s).

(iii) The identity of each collabora-
tion agent that received a distribution
payment.
Centers for Medicare & Medicaid Services, HHS § 512.510

(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 FFS for items and services furnished by the downstream collaboration agent to the EPM participant's