Centers for Medicare & Medicaid Services, HHS § 512.500

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 EPM.

(2) Remedial actions include the following:

(i) Issuing a warning letter to the EPM participant.

(ii) Requiring the EPM participant to develop a corrective action plan, commonly referred to as a CAP.

(iii) Reducing or eliminating the EPM participant’s reconciliation payment.

(iv) Reducing or eliminating the EPM participant’s CR incentive payment.

(v) Requiring the EPM participant to terminate a sharing arrangement with an EPM collaborator and prohibit further engagement by the EPM participant in sharing arrangements with the EPM collaborator.

(vi) Terminating the EPM participant’s participation in the EPM. Where a participant is terminated from an EPM, the EPM participant will remain liable for all negative NPRA generated from EPM episodes that ended prior to termination.

(3) CMS may add a 25-percent penalty to a repayment amount on the EPM participant’s reconciliation report if all of the following conditions are met:

(i) CMS has required a corrective action plan from the EPM participant.

(ii) The EPM participant owes a repayment amount to CMS.

(iii) The EPM participant fails to timely comply with the corrective action plan or is noncompliant with the EPM’s requirements.

Subpart F—Financial Arrangements and Beneficiary Incen-
tives

§ 512.500 Sharing arrangements under the EPM.

(a) General. (1) An EPM participant may enter into a sharing arrangement with an EPM collaborator to make a gainsharing payment, or to receive an alignment payment, or both. An EPM participant must not make a gainsharing payment or receive an alignment payment except in accordance with a sharing arrangement.

(2) A sharing arrangement must comply with the provisions of this section and all other applicable laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements.

(3) The EPM participant must develop, maintain, and use a set of written policies for selecting individuals and entities to be EPM collaborators. These policies must contain criteria related to, and inclusive of, the quality of care delivered by the potential EPM collaborator. The selection criteria cannot be based 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. A selection criterion that considers whether a potential EPM collaborator has performed a reasonable minimum number of services that would qualify as EPM activities will be deemed not to violate the volume or value standard if the purpose of the criterion is to ensure the quality of care furnished to EPM beneficiaries.

(b) Requirements. (1) A sharing arrangement must be in writing and signed by the parties, and entered into before care is furnished to EPM beneficiaries under the sharing arrangement.

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

(3) The sharing arrangement must require the EPM collaborator and its employees, contractors (including collaboration agents), and subcontractors (including downstream collaboration agents) to comply with all of the following:

(i) The applicable provisions of this part (including requirements regarding beneficiary notifications, access to
records, record retention, and participation in any evaluation, monitoring, compliance, and enforcement activities performed by CMS or its designees).

(ii) All applicable Medicare provider enrollment requirements at §424.500 of this chapter, including having a valid and active TIN or NPI, during the term of the sharing arrangement.

(iii) All other applicable laws and regulations.

(4) The sharing arrangement must require the EPM collaborator to have or be covered by a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of the EPM that apply to its role as an EPM collaborator, including any distribution arrangements.

(5) The sharing arrangement must not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care.

(6) The board or other governing body of the EPM participant must have responsibility for overseeing the EPM participant’s participation in the EPM, its arrangements with EPM collaborators, its payment of gainsharing payments, its receipt of alignment payments, and its use of beneficiary incentives in the EPM.

(7) The written agreement memorializing a sharing arrangement must specify the following:

(i) The purpose and scope of the sharing arrangement;

(ii) The identities and obligations of the parties, including specified EPM activities and other services to be performed by the parties under the sharing arrangement;

(iii) The date of the sharing arrangement;

(iv) The financial or economic terms for payment, including the following:

(A) Eligibility criteria for a gainsharing payment.

(B) Eligibility criteria for an alignment payment.

(C) Frequency of gainsharing or alignment payment.

(D) Methodology and accounting formula for determining the amount of a gainsharing payment that is substantially based on quality of care and the provision of EPM activities.

(E) Methodology and accounting formula for determining the amount of an alignment payment.

(8) The sharing arrangement must not—

(i) Induce the EPM participant, EPM collaborator, or any employees, contractors, or subcontractors of the EPM participant or EPM collaborator to reduce or limit medically necessary services to any Medicare beneficiary; or

(ii) Restrict the ability of an EPM collaborator to make decisions in the best interests of its patients, including the selection of devices, supplies, and treatments.

(c) Gainsharing payment, alignment payment, and internal cost savings conditions and restrictions.

(1) Gainsharing payments, if any, must—

(i) Be derived solely from reconciliation payments, or internal cost savings, or both;

(ii) Be distributed on an annual basis (not more than once per calendar year);

(iii) Not be a loan, advance payment, or payment for referrals or other business; and

(iv) Be clearly identified as a gainsharing payment at the time it is paid.

(2)(i) To be eligible to receive a gainsharing payment, an EPM collaborator must meet quality of care criteria for the performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment. The quality of care criteria must be established by the EPM participant and directly related to EPM episodes.

(ii) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, an EPM collaborator other than an ACO, PGP, NPPGP, or TGP must have directly furnished a billable item or service to an EPM beneficiary during an EPM episode that occurred in the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount.

(iii) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, an
EPM collaborator that is a PGP, NPPGP, or TGP must meet the following criteria:

(A) The PGP, NPPGP, or TGP must have billed for an item or service that was rendered by one or more PGP member, NPPGP member, or TGP member respectively 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 or was assessed a repayment amount.

(B) The PGP, NPPGP, or TGP must have contributed to EPM activities and been clinically involved in the care of EPM beneficiaries 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 or was assessed a repayment amount. For example, a PGP, NPPGP, or TGP might have been clinically involved in the care of EPM beneficiaries by—

(1) Providing care coordination services to EPM beneficiaries during and/or after inpatient admission;

(2) Engaging with an EPM participant in care redesign strategies, and actually performing a role in implementing such strategies, that are designed to improve the quality of care and reduce spending for EPM episodes; or

(3) In coordination with other providers and suppliers (such as PGP members, NPPGP members, or TGP members; the EPM participant; and post-acute care providers), implementing strategies designed to address and manage the comorbidities of EPM beneficiaries.

(iv) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, an EPM collaborator that is an ACO must meet the following criteria:

(A) The ACO must have had an ACO provider/supplier that directly furnished, or an ACO participant that billed for, an item or service that was 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 gainsharing payment or was assessed a repayment amount; and

(B) The ACO must have contributed to EPM activities and been clinically involved in the care of EPM beneficiaries 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 or was assessed a repayment amount. For example, an ACO might have been clinically involved in the care of EPM beneficiaries by—

(1) Providing care coordination services to EPM beneficiaries during and/or after inpatient admission;

(2) Engaging with an EPM participant in care redesign strategies, and actually performing a role in implementing such strategies, that are designed to improve the quality of care and reduce spending for EPM episodes; or

(3) In coordination with providers and suppliers (such as ACO participants, ACO provider/suppliers, the ACO participant, and post-acute care providers), implementing strategies designed to address and manage the comorbidities of EPM beneficiaries.

(3)(i) The methodology for accruing, calculating and verifying internal cost savings must be transparent, measurable, and verifiable in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book).

(ii) The methodology used to calculate internal cost savings must reflect the actual, internal cost savings achieved by the EPM participant through the documented implementation of EPM activities identified by the EPM participant and must exclude:

(A) Any savings realized by any individual or entity that is not the EPM participant; and

(B) “Paper” savings from accounting conventions or past investment in fixed costs.

(4) The total amount of a gainsharing payment for a performance year paid to certain individuals and entities that are EPM collaborators must not exceed the following:
(i) In the case of an EPM collaborator who is a physician or nonphysician practitioner, 50 percent of the Medicare-approved amounts under the PFS for items and services furnished by that physician or nonphysician practitioner to the EPM participant’s 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 gainsharing payment being made.

(ii) In the case of an EPM collaborator that is a PGP or NPPGP, 50 percent of the Medicare-approved amounts under the PFS for items and services billed by that PGP or NPPGP and furnished to the EPM participant’s EPM beneficiaries by the PGP members or NPPGP members respectively 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 gainsharing payment being made.

(5) The amount of any gainsharing payments must be determined in accordance with a methodology that is substantially based on quality of care and the provision of EPM activities. The methodology may take into account the amount of such EPM activities provided by an EPM collaborator relative to other EPM collaborators.

(6) For a performance year, the aggregate amount of all gainsharing payments that are derived from a reconciliation payment the EPM participant receives from CMS must not exceed the amount of that reconciliation payment.

(7) No entity or individual, whether a party to a sharing arrangement or not, may condition the opportunity to make or receive gainsharing payments or to make or receive alignment payments 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.

(8) An EPM participant must not make a gainsharing payment to an EPM collaborator if CMS has notified the EPM participant that such collaborator is subject to any action for noncompliance with this part or the fraud and abuse laws, or for the provision of substandard care to EPM beneficiaries or other integrity problems.

(9) The sharing arrangement must require the EPM participant to recoup any 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.

(10) Alignment payments from an EPM collaborator to an EPM participant may be made at any interval that is agreed upon by both parties, and must not be—

(i) Issued, distributed, or paid prior to the calculation by CMS of a repayment amount reflected in a reconciliation report;

(ii) Loans, advance payments, or payments for referrals or other business; or

(iii) Assessed by an EPM participant if it does not owe a repayment amount.

(11) The EPM participant must not receive any amounts under a sharing arrangement from an EPM collaborator that are not alignment payments.

(12) For a performance year, the aggregate amount of all alignment payments received by the EPM participant must not exceed 50 percent of the EPM participant’s repayment amount.

(13) The aggregate amount of all alignment payments from an EPM collaborator to the EPM participant may not be greater than—

(i) With respect to an EPM collaborator other than an ACO, 25 percent of the EPM participant’s repayment amount; or

(ii) With respect to an EPM collaborator that is an ACO, 50 percent of the EPM participant’s repayment amount.

(14) The amount of any alignment payments must be determined in accordance with a methodology that does not directly account for the volume or value of past or anticipated referrals or
§ 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.

§ 512.505 Distribution arrangements under the EPM.