§ 512.460 Discharge planning notice. An EPM participant must provide the beneficiary with a written notice of any potential financial liability associated with non-covered services recommended or presented as an option as part of discharge planning, no later than at the time that the beneficiary discusses a particular post-acute care option or at the time the beneficiary is discharged, whichever occurs earlier.

(i) If the EPM participant knows or should have known that the beneficiary is considering or has decided to receive a non-covered post-acute care service or other non-covered associated service or supply, the EPM participant must notify the beneficiary that the service would not be covered by Medicare.

(ii) If the EPM participant is discharging a beneficiary to a SNF prior to the occurrence of a 3-day hospital stay, and the beneficiary is being transferred to or is considering a SNF that would not qualify under the SNF 3-day waiver in §512.610, the EPM participant must notify the beneficiary in accordance with paragraph (b)(3)(i) of this section that the beneficiary will be responsible for payment for the services furnished by the SNF during that stay, except those services that would be covered by Medicare Part B during a non-covered inpatient SNF stay.

(4) Access to records and retention. Lists of beneficiaries that receive notifications or notices must be retained and access provided to CMS, or its designees, in accordance with §512.110.

§ 512.460 Compliance enforcement.

(a) General. EPM participants must comply with all of the requirements outlined in this part. Except as specifically noted in this part, the regulations under this part must not be construed to affect the applicable payment, coverage, program integrity, or other requirements under this chapter (such as those in parts 412 and 482 of this chapter).

(b) Failure to comply. (1) CMS may take one or more of the remedial actions set forth in paragraph (b)(2) of this section if an EPM participant or its related EPM collaborator, collaboration agent, or downstream collaboration agent does any of the following:

(i) Fails to comply with any requirements of this part or is identified as noncompliant through monitoring by HHS (including CMS and OIG) of the EPM, including, but not limited to, any of the following:

(A) Avoiding potentially high-cost or high-severity patients.

(B) Targeting potentially low-cost or low-severity patients.

(C) Failing to provide medically appropriate services or systematically engaging in the over- or under-delivery of appropriate care.

(D) Failing to provide beneficiaries with complete and accurate information, including required notices.

(E) Failing to allow beneficiary choice of medically necessary options, including non-surgical options.

(F) Failing to follow the requirements related to sharing arrangements.

(ii) Has signed a sharing arrangement, distribution arrangement, or downstream distribution arrangement that is noncompliant with the requirements of this part.

(iii) Takes any action that threatens the health or safety of patients.

(iv) Avoids at-risk Medicare beneficiaries, as this term is defined in §425.20 of this chapter.

(v) Avoids patients on the basis of payer status.

(vi) Is subject to sanctions or final actions of an accrediting organization or Federal, state, or local government agency that could lead to the inability to comply with the requirements and provisions of this part.

(vii) Takes any action that CMS determines for program integrity reasons is not in the best interests of the EPM, or fails to take any action that CMS determines for program integrity reasons should have been taken to further the best interests of the EPM.

(viii) Is subject to action by HHS (including OIG and CMS) or the Department of Justice to redress an allegation of fraud or significant misconduct, including intervening in a False Claims Act qui tam matter, issuing a pre-demand or demand letter under a civil sanction authority, or similar actions.

(ix) Is subject to action involving violations of the physician self-referral
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 Incentives

§ 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.

(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