§ 512.450 Beneficiary choice and beneficiary notification.

(a) Beneficiary choice. The EPMs do not restrict Medicare beneficiaries’ ability to choose any Medicare enrolled provider or supplier, or any physician or practitioner who has opted out of Medicare.

(1) As part of discharge planning and referral, EPM participants must provide a complete list of HHAs, SNFs, IRFs, or LTCHs that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of a SNF, IRF, or LTCH services are medically necessary.

(b) Required beneficiary notification—

(1) EPM participant detailed notification. Each EPM participant must provide written notification to any Medicare beneficiary that meets the criteria in §512.240 of his or her inclusion in the EPM. The notification must be provided upon admission to the EPM participant if the admission that initiates the EPM episode is not scheduled with the EPM participant in advance. If the admission is scheduled in advance, then the EPM participant must provide notice as soon as the admission is scheduled. In circumstances where, due to the patient’s condition, it is not feasible to provide notification at such times, the notification must be provided to the beneficiary or his or her representative as soon as is reasonably practicable but no later than discharge from the EPM participant accountable for the EPM episode. The EPM participant must be able to generate a list of all beneficiaries receiving such notification, including the date on which the
notification was provided to the beneficiary, to CMS upon request. The beneficiary notification must contain all of the following:

(i) A detailed explanation of the EPM and how it might be expected to affect the beneficiary’s care.

(ii) Notification that the beneficiary retains freedom of choice to choose providers and services.

(iii) Explanation of how patients can access care records and claims data through an available patient portal, and how they can share access to their Blue Button® electronic health information with caregivers.

(iv) A statement that all existing Medicare beneficiary protections continue to be available to the beneficiary. These include the ability to report concerns of substandard care to Quality Improvement Organizations or the 1-800-MEDICARE helpline.

(v) A list of the providers, suppliers, and ACOs with whom the EPM participant has a sharing arrangement. This requirement may be fulfilled by the EPM participant including in the detailed notification a web address where beneficiaries may access the list.

(2) EPM collaborator notice. An EPM participant must require every EPM collaborator to provide written notice to applicable EPM beneficiaries of the structure of the EPM and the existence of its sharing arrangement with the EPM participant.

(i) An EPM participant must require every EPM collaborator that furnishes an item or service to an EPM beneficiary during an EPM episode to provide written notice to the beneficiary of the structure of the EPM and the existence of its sharing arrangement. The notice must be provided no later than the time at which the beneficiary first receives an item or service from any provider or supplier or ACO participant or ACO provider/supplier and the required notice may be provided by that provider or supplier. In circumstances where, due to the patient’s condition, it is not feasible to provide notice at such times, the notice must be provided to the beneficiary or his or her representative as soon as is reasonably practicable. The EPM collaborator must be able to generate a list of all beneficiaries who received such a notice, including the date on which the notice was provided to the beneficiary, to CMS upon request.

(ii) An EPM participant must require every EPM collaborator that is a PGP, NPPGP, or TGP where a member of the PGP, member of the NPPGP, or member of the TGP furnishes an item or service to an EPM beneficiary during an EPM episode to provide written notice to the beneficiary of the structure of the EPM and the existence of the entity’s sharing arrangement. The notice must be provided no later than the time at which the beneficiary first receives an item or service from any member of the PGP, member of the NPPGP, or member of the TGP, and the required notice may be provided by that member. In circumstances where, due to the patient’s condition, it is not feasible to provide notice at such times, the notice must be provided to the beneficiary or his or her representative as soon as is reasonably practicable. The PGP, NPPGP, or TGP must be able to generate a list of all beneficiaries who received such a notice, including the date on which the notice was provided to the beneficiary, to CMS upon request.

(iii) An EPM participant must require every EPM collaborator that is an ACO where an ACO participant bills for or ACO provider/supplier furnishes an item or service to an EPM beneficiary during an EPM episode to provide written notice to the beneficiary of the structure of the EPM and the existence of the entity’s sharing arrangement. The notice must be provided no later than the time at which the beneficiary first receives an item or service from any ACO participant or ACO provider/supplier and the required notice may be provided by that ACO participant or ACO provider/supplier. In circumstances where, due to the patient’s condition, it is not feasible to provide notice at such times, the notice must be provided to the beneficiary or his or her representative as soon as is reasonably practicable. The ACO must be able to generate a list of all beneficiaries who received such a notice, including the date on which the notice was provided to the beneficiary, to CMS or its designee upon request.
§ 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