

510.410 Compliance enforcement.

(a) General. Participant hospitals 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 payment, coverage, program integrity, or other requirements (such as those in parts 412 and 482 of this chapter) that apply to providers and suppliers under 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 a participant hospital or its related CJR collaborators, collaboration agents, or downstream collaboration agents -

(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 CJR model, including but not limited to the following:

(A) Avoiding potentially high cost patients.

(B) Targeting potentially low cost 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.

(G) Failing to participate in CJR model-related evaluation activities conducted by CMS or its contractors or both.

(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;

(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 CJR model, or fails to take any action that CMS determines for program integrity reasons should have been taken to further the best interests of the CJR model;

(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; or

(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 CJR model.

(2) Remedial actions include the following:

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

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

(iii) Reducing or eliminating a participant hospital's reconciliation payment.

(iv) Requiring a participant hospital to terminate a sharing arrangement with a CJR collaborator and prohibiting further engagement in sharing arrangements with the participant hospital by that CJR collaborator.

(v) Terminating the participant hospital's participation in the CJR model. Where a participant is terminated from the CJR model, the participant hospital will remain liable for all negative NPRA generated from episodes of care that ended prior to termination.

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

(i) CMS has required a corrective action plan from a participant hospital;

(ii) The participant hospital owes a repayment amount to CMS; and

(iii) The participant hospital fails to timely comply with the corrective action plan or is noncompliant with the CJR model's requirements.