

513.440 Enforcement authority.

(a) Remedial action - (1) Grounds for remedial action. In addition to any other grounds for remedial action that are permitted under the terms of this part, CMS may take one or more of the remedial actions set forth in paragraph (a)(2) of this section if CMS determines, in CMS' sole discretion, that an MFN participant:

- (i) Has failed to comply with any applicable Medicare program requirement, rule, or regulation.
- (ii) Has failed to comply with any of the terms of the MFN Model, including applicable requirements of this part.
- (iii) Has systematically engaged in the under delivery or over delivery of an MFN Model drug.
- (iv) Has taken any action that threatens the health or safety of an MFN beneficiary or other patient.
- (v) Has undergone a change of control that presents a program integrity risk.
- (vi) Has submitted false data or made false representations, warranties, certifications or attestations in connection with any aspect of the MFN Model.
- (vii) Has avoided at-risk beneficiaries, as this term is defined in § 425.20 of this chapter.
- (viii) Has avoided patients on the basis of payer status.
- (ix) Is subject to sanctions or final actions of an accrediting organization or Federal, State, or local government agency.
- (x) Takes any action that CMS determines for program integrity reasons is not in the best interests of the MFN Model or the Medicare program, or fails to take any action that CMS determines for program integrity reasons should have been taken to further the best interests of the MFN Model or Medicare program.
- (xi) Is subject to investigation by HHS (including the HHS Office of Inspector General (OIG)) or the Department of Justice due to an allegation of fraud or significant misconduct, including being subject to the filing of a complaint, filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the Federal Government has intervened, or similar action;
- (xii) Is the subject of administration enforcement action imposed by CMS; or
- (xiii) Has failed to demonstrate improved performance following any remedial action imposed under this section.

(2) Taking remedial actions. If CMS determines that one or more grounds for remedial action described in paragraph (a)(1) of this section exist, CMS make take one or more of the following remedial actions:

(i) Notifying the MFN participant of the violation.

(ii) Requiring the MFN participant to provide additional information to CMS or its designees.

(iii) Requiring the MFN participant to develop and implement a corrective action plan in a form and manner and by a deadline specified by CMS.

(iv) Subjecting the MFN participant to additional monitoring, auditing, or both.

(v) Removing the MFN participant from the MFN Model.

(vi) Recouping model-specific payments.

(vii) Other action as may be permitted under the terms of this part.

(b) OIG authority. Nothing contained in the terms of the MFN Model or this part limits or restricts the authority of the HHS Office of Inspector General or any other Federal Government authority or agency, including its authority to audit, evaluate, investigate, or inspect model participant for violations of any statutes, rules, or regulations administered by the Federal Government.