

# 513.420 Monitoring and compliance activities.

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(a) Compliance with laws. (1) Agreement to comply. The MFN participant must comply with all applicable laws and regulations.

(2) Notification. The MFN participant must notify CMS within 15 days after becoming aware that the MFN participant is under investigation or has been sanctioned by the federal, state, or local government, or any licensing authority (including, without limitation, the imposition of program exclusion, debarment, civil monetary penalties, corrective action plans, and revocation of Medicare billing privileges).

(b) CMS monitoring and compliance activities. (1) CMS conducts monitoring activities to ensure compliance by MFN participants with the terms of the MFN Model, to obtain timely information about the effects of the MFN Model on MFN beneficiaries, providers, suppliers, and on the Medicare program and to facilitate real time identification and response to potential issues. Such monitoring activities may include, without limitation, the following:

(i) Documentation requests sent to the MFN participant including, without limitation, surveys and questionnaires.

(ii) Audits of claims data, medical records, and other data from the MFN participant.

(iii) Interviews with any individual or entity participating in the MFN Model including members of the MFN participant's leadership, management, and staff.

(iv) Interviews with beneficiaries and their caregivers.

(v) Site visits to the MFN participants, performed in a manner consistent with § 513.420(c).

(vi) Tracking patient complaints and appeals.

(2) In conducting monitoring and oversight activities, CMS or its designees may use any relevant data or information including without limitation, all Medicare claims submitted for items or services furnished to beneficiaries in the MFN Model.

(3) The MFN participant must cooperate with evaluation and monitoring activities as may be necessary to enable CMS to evaluate the MFN Model in accordance with section 1115A(b)(4) of the Act and to conduct monitoring activities under this section.

(c) Site visits. (1) To the extent practicable, CMS or its designee provides the MFN participant with no less than 15 days advance notice of any site visit. To the extent practicable, CMS attempts to accommodate a request for particular dates in scheduling site

visits. However, the MFN participant may not request a date that is more than 60 days after the date of the initial site visit notice from CMS.

(2) The MFN participant must ensure that personnel with the appropriate responsibilities and knowledge associated with the purpose of the site visit are available during all site visits.

(3) Notwithstanding the foregoing, CMS may perform unannounced site visits at all physical locations of the MFN participant at any time to investigate concerns about the health or safety of beneficiaries or other patients or other program integrity issues.

(4) Nothing in this part must be construed to limit or otherwise prevent CMS from performing site visits permitted or required by applicable law.

(d) Right to correct. If CMS discovers that it has made or received an incorrect model-specific payment under the terms of the MFN Model, CMS may make payment to, or demand payment from, the MFN participant.