512.150 Monitoring and compliance.

(a) Compliance with laws. The model participant and each of its downstream participants must comply with all applicable laws and regulations.

(b) CMS monitoring and compliance activities. (1) CMS may conduct monitoring activities to ensure compliance by the model participant and each of its downstream participants with the terms of the Innovation Center model including this subpart; to understand model participants' use of model-specific payments; and to promote the safety of beneficiaries and the integrity of the Innovation Center model. Such monitoring activities may include, without limitation, all of the following:

(i) Documentation requests sent to the model participant and its downstream participants, including surveys and questionnaires.

(ii) Audits of claims data, quality measures, medical records, and other data from the model participant and its downstream participants.

(iii) Interviews with members of the staff and leadership of the model participant and its downstream participants.

(iv) Interviews with beneficiaries and their caregivers.

(v) Site visits to the model participant and its downstream participants, performed in a manner consistent with paragraph (c) of this section.

(vi) Monitoring quality outcomes and clinical data, if applicable.

(vii) 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 model beneficiaries.

(c) Site visits. (1) In a manner consistent with § 512.130, the model participant and its downstream participants must cooperate in periodic site visits performed by CMS or its designees in order to facilitate the evaluation of the Innovation Center model and the monitoring of the model participant's compliance with the terms of the Innovation Center model, including this subpart.

(2) CMS or its designee provides, to the extent practicable, the model participant or downstream participant with no less than 15 days advance notice of any site visit. CMS -

(i) Will attempt, to the extent practicable, to accommodate a request for particular dates in scheduling site visits.

(ii) Will not accept a date request from a model participant or downstream participant that is more than 60 days after the date of the CMS initial site visit notice.

(3) The model participant and its downstream participants must ensure that personnel with the appropriate responsibilities and knowledge associated with the purpose of the site visit are available during all site visits.

(4) Additionally, CMS may perform unannounced site visits at the office of the model participant and any of its downstream participants at any time to investigate concerns about the health or safety of beneficiaries or other patients or other program integrity issues.

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

(d) Reopening of payment determinations. (1) CMS may reopen a model-specific payment determination on its own motion or at the request of a model participant, within 4 years from the date of the determination, for good cause (as defined at § 405.986 of this chapter).

(2) CMS may reopen a model-specific payment determination at any time if there exists reliable evidence (as defined in § 405.902 of this chapter) that the determination was procured by fraud or similar fault (as defined in § 405.902 of this chapter).

(3) CMS's decision regarding whether to reopen a model-specific payment determination is binding and not subject to appeal.

(e) OIG authority. Nothing contained in the terms of the Innovation Center Model or this part limits or restricts the authority of the HHS Office of Inspector General or any other Federal government authority, including its authority to audit, evaluate, investigate, or inspect the model participant or its downstream participants for violations of any Federal statutes, rules, or regulations.