

512.135 Audits and record retention.

(a) Right to audit. The Federal government, including CMS, HHS, and the Comptroller General, or their designees, has the right to audit, inspect, investigate, and evaluate any documents and other evidence regarding implementation of an Innovation Center model.

(b) Access to records. The model participant and its downstream participants must maintain and give the Federal government, including CMS, HHS, and the Comptroller General, or their designees, access to all such documents and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the implementation of the Innovation Center model, including without limitation, documents and other evidence regarding all of the following:

(1) The model participant's and its downstream participants' compliance with the terms of the Innovation Center model, including this subpart.

(2) The accuracy of model-specific payments made under the Innovation Center model.

(3) The model participant's payment of amounts owed to CMS under the Innovation Center model.

(4) Quality measure information and the quality of services performed under the terms of the Innovation Center model, including this subpart.

(5) Utilization of items and services furnished under the Innovation Center model.

(6) The ability of the model participant to bear the risk of potential losses and to repay any losses to CMS, as applicable.

(7) Patient safety.

(8) Other program integrity issues.

(c) Record retention. (1) The model participant and its downstream participants must maintain the documents and other evidence described in paragraph (b) of this section and other evidence for a period of six years from the last payment determination for the model participant under the Innovation Center model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless -

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the model participant at least 30 days before the normal disposition date; or

(ii) There has been a termination, dispute, or allegation of fraud or similar fault against the model participant or its downstream participants, in which case the records must be

maintained for an additional 6 years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

(2) If CMS notifies the model participant of the special need to retain records in accordance with paragraph (c)(1)(i) of this section or there has been a termination, dispute, or allegation of fraud or similar fault against the model participant or its downstream participants described in paragraph (c)(1)(ii) of this section, the model participant must notify its downstream participants of this need to retain records for the additional period specified by CMS.