

§ 512.105

42 CFR Ch. IV (10–1–17 Edition)

(viii) 37.90 (Insertion of left atrial appendage device).

§ 512.105 Geographic areas.

(a) The SHFFT model must be implemented in the same geographic areas as the CJR model as described under § 510.105 of the chapter.

(b) The geographic areas for inclusion in the CABG and AMI models will be obtained using a random sampling of certain MSAs in the United States. All counties within each of the selected MSAs are selected for inclusion in the AMI and CABG models. CMS excludes MSAs that met the following criteria between January 1, 2014 and December 31, 2014 from the possibility of being selected geographic areas. MSAs are excluded if they—

(1) Had fewer than 75 AMI episodes;
(2) Had fewer than 75 AMI episodes that were not attributable to BPCI Model 2 or 4, AMI, CABG or PCI episodes;

(3) Had more than 50 percent of otherwise qualifying (BPCI or non BPCI) episodes attributable to a BPCI Model 2 or 4 AMI, CABG or PCI episodes; or

(4) Are in Maryland, Vermont, or another state where CMS is implementing a state-wide all-payer model. In such situations all MSAs in the state may be excluded even if hospitals are otherwise being paid in accordance with the IPPS and would otherwise qualify as an eligible EPM participant.

(c) In all geographic areas where the AMI, CABG, or SHFFT models are being implemented, the accountable financial entity must be an acute care IPPS hospital.

§ 512.110 Access to records and retention.

EPM participants, EPM collaborators, collaboration agents, downstream collaboration agents, and any other individuals or entities performing EPM activities must:

(a) Allow the Government, including CMS, OIG, HHS, and the Comptroller General or their designees, scheduled and unscheduled access to all books, contracts, records, documents, and other evidence (including data related to utilization and payments, quality of care criteria, billings, lists of EPM collaborators, sharing arrangements, dis-

tribution arrangements, downstream distribution arrangements, and the documentation required under §§ 512.500(d) and 512.525(d)) sufficient to enable the audit, evaluation, inspection, or investigation of the following:

(1) The individual's or entity's compliance with EPM requirements and, if applicable, the individual's or entity's compliance with CR incentive payment model requirements.

(2) The calculation, distribution, receipt, or recoupment of gainsharing payments, alignment payments, distribution payments, and downstream distribution payments.

(3) The obligation to repay any reconciliation payments or CR incentive payments, if applicable, owed to CMS.

(4) The quality of the services furnished to an EPM beneficiary during an EPM episode.

(5) The sufficiency of EPM beneficiary notifications.

(6) The accuracy of the EPM participant's submissions under CEHRT use requirements.

(b) Maintain all such books, contracts, records, documents, and other evidence for a period of 10 years from the last day of the EPM participant's participation in the EPM or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

(1) CMS determines a particular record or group of records should be retained for a longer period and notifies the EPM participant at least 30 calendar days before the disposition date; or

(2) There has been a dispute or allegation of fraud or similar fault against the EPM participant, EPM collaborator, collaboration agent, downstream collaboration agent, or any other individual or entity performing EPM activities in which case the records must be maintained for 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault.

§ 512.120 EPM participant CEHRT track requirements.

(a) *EPM CEHRT use.* For performance year 2 if the EPM participant elects downside risk and for performance

years 3 through 5, EPM participants choose either of the following:

(1) *CEHRT use.* EPM participants attest in a form and manner specified by CMS to their use of CEHRT as defined in §414.1305 of this chapter to document and communicate clinical care with patients and other health professionals.

(2) *No CEHRT use.* EPM participants do not attest in a form and manner specified by CMS to their use of CEHRT as defined in §414.1305 of this chapter to document and communicate clinical care with patients and other health professionals.

(b) *Clinician financial arrangements list.* Each EPM participant that chooses CEHRT use as provided in paragraph (a)(1) of this section must submit to CMS a clinician financial arrangements list in a form and manner specified by CMS on a no more than quarterly basis. The list must include the following information on individuals and entities for the period of the EPM performance year specified by CMS:

(1) *EPM collaborators.* For each physician, nonphysician practitioner, or therapist in private practice who is an EPM collaborator during the period of the EPM performance year specified by CMS:

(i) The name, TIN, and NPI of the EPM collaborator.

(ii) The start date and, if applicable, end date, for the sharing arrangement between the EPM participant and the EPM collaborator.

(2) *Collaboration agents.* For each physician, nonphysician practitioner, or therapist who is a collaboration agent during the period of the EPM performance year specified by CMS:

(i) The name and TIN of the EPM collaborator and the name, TIN, and NPI of the collaboration agent.

(ii) The start date and, if applicable, end date, for the distribution arrangement between the EPM collaborator and the collaboration agent.

(3) *Downstream collaboration agents.* For each physician, nonphysician practitioner, or therapist who is a downstream collaboration agent during the period of the EPM performance year specified by CMS:

(i) The name and TIN of the EPM collaborator, the name and TIN of the collaboration agent and the name, TIN,

and NPI of the downstream collaboration agent.

(ii) The start date and, if applicable, end date, for the downstream distribution arrangement between the collaboration agent and the downstream collaboration agent.

(4) *Attestation to no individuals.* If there are no individuals that meet the requirements to be reported, as specified in paragraphs (b)(1) through (3) of this section, the EPM participant must attest in a form and manner required by CMS that there are no individuals to report on the clinician financial arrangements list.

(c) *Documentation requirements.* (1) Each EPM participant that chooses CEHRT use as provided in paragraph (a)(1) of this section must maintain documentation of their attestation to CEHRT use and clinician financial arrangements lists.

(2) The EPM participant must retain and provide access to the required documentation in accordance with §512.110.

Subpart C—Scope of Episodes

§512.200 Time periods for EPM episodes.

All AMI, CABG, and SHFFT episodes begin on or after July 1, 2017 and end on or before December 31, 2021.

§512.210 Included and excluded services.

(a) *Included services for an EPM.* All Medicare Parts A and B items and services are included in the EPM episode, except as specified in paragraph (b) of this section. These services include, but are not limited to, the following:

- (1) Physicians' services.
- (2) Inpatient hospital services.
- (3) IPF services.
- (4) LTCH services.
- (5) IRF services.
- (6) SNF services.
- (7) HHA services.
- (8) Hospital outpatient services.
- (9) Independent outpatient therapy services.
- (10) Clinical laboratory services.
- (11) DME.
- (12) Part B drugs and biologicals.
- (13) Hospice.