premium equals the Medicaid capitation amount.

(b) Medicare Part A only. For a participant who is entitled to Medicare Part A, not enrolled under Medicare Part B, and not eligible for Medicaid, the premium equals the Medicaid capitation amount plus the Medicare Part B capitation rate.

(c) Medicare Part B only. For a participant who is enrolled only under Medicare Part B and not eligible for Medicaid, the premium equals the Medicaid capitation amount plus the Medicare Part A capitation rate.

(d) Medicaid, with or without Medicare. A PACE organization may not charge a premium to a participant who is eligible for both Medicare and Medicaid, or who is only eligible for Medicaid.

Subpart K—Federal/State Monitoring

§ 460.190 Monitoring during trial period.

(a) Trial period review. During the trial period, CMS, in cooperation with the State administering agency, conducts comprehensive annual reviews of the operations of a PACE organization to ensure compliance with the requirements of this part.

(b) Scope of review. The review includes the following:

(1) An onsite visit to the PACE organization, which may include, but is not limited to, the following:
   (i) Review of participants’ charts.
   (ii) Interviews with staff.
   (iii) Interviews with participants and caregivers.
   (iv) Interviews with contractors.
   (v) Observation of program operations, including marketing, participant services, enrollment and disenrollment procedures, grievances, and appeals.

(2) A comprehensive assessment of an organization’s fiscal soundness.

(3) A comprehensive assessment of the organization’s capacity to furnish all PACE services to all participants.

(4) Any other elements that CMS or the State administering agency find necessary.

§ 460.192 Ongoing monitoring after trial period.

(a) At the conclusion of the trial period, CMS, in cooperation with the State administering agency, continues to conduct reviews of a PACE organization, as appropriate, taking into account the quality of care furnished and the organization’s compliance with all of the requirements of this part.

(b) Reviews include an on-site visit at least every 2 years.

§ 460.194 Corrective action.

(a) A PACE organization must take action to correct deficiencies identified during reviews.

(b) CMS or the State administering agency monitors the effectiveness of corrective actions.

(c) Failure to correct deficiencies may result in sanctions or termination, as specified in subpart D of this part.

§ 460.196 Disclosure of review results.

(a) CMS and the State administering agency promptly report the results of reviews under §§460.190 and 460.192 to the PACE organization, along with any recommendations for changes to the organization’s program.

(b) CMS and the State administering agency make the results of reviews available to the public upon request.

(c) The PACE organization must make the review results available for examination in a place readily accessible to participants.

Subpart L—Data Collection, Record Maintenance, and Reporting

§ 460.200 Maintenance of records and reporting of data.

(a) General rule. A PACE organization must collect data, maintain records, and submit reports as required by CMS and the State administering agency.

(b) Access to data and records. A PACE organization must allow CMS and the State administering agency access to