

**§ 460.80**

**42 CFR Ch. IV (10-1-02 Edition)**

daily nutritional needs of a participant, if indicated by his or her medical condition or diagnosis. Nutrition support consists of tube feedings, total parenteral nutrition, or peripheral parenteral nutrition.

(b) *Sanitary conditions.* The PACE organization must do the following:

(1) Procure foods (including nutritional supplements and nutrition support items) from sources approved, or considered satisfactory, by Federal, State, Tribal, or local authorities with jurisdiction over the service area of the organization.

(2) Store, prepare, distribute, and serve foods (including nutritional supplements and nutrition support items) under sanitary conditions.

(3) Dispose of garbage and refuse properly.

**§ 460.80 Fiscal soundness.**

(a) *Fiscally sound operation.* A PACE organization must have a fiscally sound operation, as demonstrated by the following:

(1) Total assets greater than total unsubordinated liabilities.

(2) Sufficient cash flow and adequate liquidity to meet obligations as they become due.

(3) A net operating surplus or a financial plan for maintaining solvency that is satisfactory to CMS and the State administering agency.

(b) *Insolvency plan.* The organization must have a documented plan in the event of insolvency, approved by CMS and the State administering agency, which provides for the following:

(1) Continuation of benefits for the duration of the period for which capitation payment has been made.

(2) Continuation of benefits to participants who are confined in a hospital on the date of insolvency until their discharge.

(3) Protection of participants from liability for payment of fees that are the legal obligation of the PACE organization.

(c) *Arrangements to cover expenses.* (1) A PACE organization must demonstrate that it has arrangements to cover expenses in the amount of at least the sum of the following in the event it becomes insolvent:

(i) One month's total capitation revenue to cover expenses the month before insolvency.

(ii) One month's average payment to all contractors, based on the prior quarter's average payment, to cover expenses the month after the date it declares insolvency or ceases operations.

(2) Arrangements to cover expenses may include, but are not limited to, the following:

(i) Insolvency insurance or reinsurance.

(ii) Hold harmless arrangement.

(iii) Letters of credit, guarantees, net worth, restricted State reserves, or State law provisions.

**§ 460.82 Marketing.**

(a) *Information that a PACE organization must include in its marketing materials.* (1) A PACE organization must inform the public about its program and give prospective participants the following written information:

(i) An adequate description of the PACE organization's enrollment and disenrollment policies and requirements.

(ii) PACE enrollment procedures.

(iii) Description of benefits and services.

(iv) Premiums.

(v) Other information necessary for prospective participants to make an informed decision about enrollment.

(2) Marketing information must be free of material inaccuracies, misleading information, or misrepresentations.

(b) *Approval of marketing information.*

(1) CMS must approve all marketing information before distribution by the PACE organization, including any revised or updated material.

(2) CMS reviews initial marketing information as part of an entity's application for approval as a PACE organization, and approval of the application includes approval of marketing information.

(3) Once a PACE organization is under a PACE program agreement, any revisions to existing marketing information and new information are subject to the following: