

TRANSMITTAL SHEET FOR  
NOTICE OF INTENDED ACTION

Control No: 560 . Department or Agency: Alabama Medicaid Agency .

Rule No: 560-X-53 .

Rule Title: Programs of All-Inclusive Care for the Elderly (PACE)

New Rule;  Amend;  Repeal;  Adoption by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare, or safety?  no  yes

Is there a reasonable relationship between the state's police power and the protection of the public health, safety, or welfare?  yes  no

Is there another, less restrictive method of regulation available that could adequately protect the public?  no  yes

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree?  no  yes

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule?  no  yes

Are all facets of the rulemaking process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public?  yes  no

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Does the proposed rule have any economic impact?  no  yes

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of Section 41-22-23, Code of Alabama 1975.

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Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama 1975 and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Reference Service.

Signature of certifying officer: 

Date: 8-17-11

\*\*\*\*\*

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**ALABAMA MEDICAID AGENCY**

**NOTICE OF INTENDED ACTION**

**RULE NO. & TITLE:** 560-X-53 – Programs of All-Inclusive Care for the Elderly (PACE)

**INTENDED ACTION:** add as new chapter.

**SUBSTANCE OF PROPOSED ACTION:** The above-referenced chapter is being added to include the new PACE Program in the Long Term Care Division. The PACE Program has been approved by CMS with an effective date of October 1, 2011.

**TIME, PLACE, MANNER OF PRESENTING VIEWS:** Written or oral comments may be submitted to the Alabama Medicaid Agency, 501 Dexter Avenue, Post Office Box 5624, Montgomery, Alabama 36103-5624, 334-242-5833. Agency business hours are 8:00 a.m. to 5:00 p.m. Monday through Friday.

**FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:**  
Written/Oral comments concerning this change must be received by the Alabama Medicaid Agency no later than November 4, 2011.

**CONTACT PERSON AT AGENCY:** Stephanie McGee Azar,  
Administrative Secretary, Alabama Medicaid Agency, 501 Dexter Avenue,  
Post Office Box 5624, Montgomery, Alabama 36103-5624.

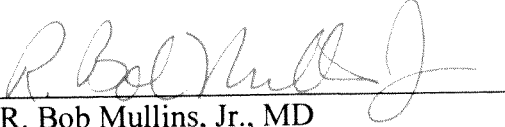
  
R. Bob Mullins, Jr., MD  
Commissioner

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**ALABAMA MEDICAID AGENCY  
LONG TERM CARE DIVISION**

**Chapter 53. Programs of All-Inclusive Care for the Elderly – NEW CHAPTER**

**560-X-53-.01. PACE Program – General.**

The Program of All-Inclusive Care for the Elderly (PACE) is a unique managed care benefit for the frail elderly population provided by a not-for-profit or public entity. The focus is to assist individuals to continue living independently at home in their communities as long as possible. The PACE program is a sole source of services for participants. It features a comprehensive medical and social service delivery system using an interdisciplinary team approach in an adult day health center setting. The services are supplemented by in-home and referral services in accordance with each participant's needs. Participation in the PACE program is voluntary.

**Author:** Linda Lackey, Medicaid Administrator, LTC Project Development Unit.

**Statutory Authority:** State Plan, Attachment 2.2-A, Attachment 3.1-A and Supplement 3; 42 CFR Part 460.

**History:** New Rule: Filed September 20, 2011.

**560-X-53-.02. Definitions.**

As used in this Rule, the following definitions apply:

- (1) PACE – Programs of All-Inclusive Care for the Elderly.
- (2) PACE Organization (PO) – entity that has an agreement with Medicaid and CMS to operate a PACE program.
- (3) PACE Center – facility operated by a PO where primary care is furnished to participants.
- (4) State Administering Agency (SAA) – state agency responsible for administering the PACE Program Agreement.
- (5) PACE Program Agreement – agreement between the State Administering Agency, CMS and PO for the operation of a PACE program.
- (6) Participant – individual who is enrolled in a PACE program.
- (7) Medicaid Participant – individual determined eligible for Medicaid who is enrolled in a PACE program.
- (8) Medicare Beneficiary – individual who is entitled to Medicare Part A benefits, or is enrolled under Medicare Part B, or both.
- (9) Medicare Participant – Medicare beneficiary who is enrolled in a PACE program.
- (10) Services – includes items and services.
- (11) Contract Year – the term of a PACE program agreement, which is a calendar year, except that the initial contract year may be from 12 to 23 months, as determined by CMS.
- (12) Trial Period – the first three contract years in which a PO operates under a PACE program agreement, including any contract year during which the entity operated

under a PACE demonstration period.

- (13) AMA – Alabama Medicaid Agency.
- (14) CMS – Center for Medicare and Medicaid Services.

**Author:** Linda Lackey, Medicaid Administrator, LTC Project Development Unit.

**Statutory Authority:** State Plan, Attachment 2.2-A, Attachment 3.1-A and Supplement 3; 42 CFR 460.6.

**History:** New Rule: Filed September 20, 2011.

**560-X-53-.03. Participant Eligibility Requirements.**

Eligibility for enrollment in PACE is not restricted to an individual who is either a Medicaid recipient or a Medicare beneficiary. Individuals eligible for enrolling in the PACE program are those included in one of the categories listed below:

- (1) Eligible for full Medicaid;
- (2) Eligible for Medicare Part A;
- (3) Enrolled under Medicare Part B;
- (4) Dual eligibles for Medicaid and Medicare.

Individuals enrolling in the PACE program must meet all of the following criteria:

- (1) Must be age 55 or older;
- (2) Certified to need nursing home care;
- (3) Able to live safely in the community at the time of enrollment; and
- (4) Live in a PACE service area.

**Author:** Linda Lackey, Medicaid Administrator, LTC Project Development Unit.

**Statutory Authority:** State Plan, Attachment 2.2-A, Attachment 3.1-A and Supplement 3; 42 CFR 460.150.

**History:** New Rule: Filed September 20, 2011.

**560-X-53-.04. Participant Enrollment.**

The enrollment application is initiated and processed by the PO as outlined in 42 CFR 460.152. The AMA will assess the potential participant to ensure that they meet the level of care requirements. Requirements for information that must be included in the enrollment agreement are in 42 CFR 460.154. Enrollment procedures that must be completed by the PO are described in 42 CFR 460.156. Requirements for continuation of enrollment are outlined in 42 CFR 460.160.

**Author:** Linda Lackey, Medicaid Administrator, LTC Project Development Unit.

**Statutory Authority:** State Plan, Attachment 2.2-A, Attachment 3.1-A and Supplement 3; 42 CFR 460 Subpart I.

**History:** New Rule: Filed September 20, 2011.

**560-X-53-.05. Participant Voluntary & Involuntary Disenrollment.**

(1) A participant may voluntarily disenroll from the PACE program at any time.

(2) A participant may be involuntarily disenrolled for any of the following reasons. Refer to 42 CFR 460.164 for guidelines to disenroll a participant.

(a) Participant fails to pay or make satisfactory arrangements to pay any premium due to the PO after a 30-day grace period;

(b) Participant moves out of PACE program service area;

(c) Participant is out of the service area for more than 30 consecutive days unless an agreement has been reached for a longer absence due to extenuating circumstances;

(d) It is determined the Participant no longer meets the level of care requirements and is deemed not eligible;

(e) The PACE agreement with CMS and AMA is not renewed or is terminated;

(f) The PO is unable to offer health care services due to the loss of State licenses or contracts with outside providers;

(g) Participant engages in disruptive or threatening behavior by:

1. jeopardizing his or her safety or the safety of others;

2. consistently refusing to comply with his or her individual plan of

care;

3. consistently refusing to comply with the terms of the enrollment

agreement.

(h) The participant no longer meets the eligibility criteria for full Medicaid or Medicare.

(3) If a PO is disenrolling a participant due to disruptive or threatening behavior, the PO must document the following information in the participant's medical record:

(a) The reasons for the disenrollment;

(b) All efforts that were made to remedy the situation.

(4) A PO must have procedures in place to document reasons for all voluntary and involuntary disenrollments. The disenrollment is to be coordinated with CMS and AMA and documentation must be made available to CMS and AMA for review. AMA must review involuntary disenrollments and determine that there is adequate documentation of the reason(s) for the involuntary disenrollment before it is effective. Information on voluntary disenrollments is to be used for the PO's internal quality assessment and performance improvement program.

(5) When disenrolling a participant, the PO is to use the most expedient process allowed under Medicaid and Medicare procedures. An advance notice of 10 days prior to the disenrollment date is to be provided to the participant.

(6) The PO must continue to furnish all services needed by the participant until

the disenrollment date. It is also required that the participant continue to use PACE services until the disenrollment date, as well as remain liable for any premiums that may be due. The disenrollment date will be the last day of the month that the participant is voluntarily or involuntarily disenrolled.

(7) The PO is to work with CMS and AMA to facilitate the reinstatement of Medicaid and Medicare programs for which the participant is eligible.

(8) A participant that has been voluntarily or involuntarily disenrolled may be reinstated in a PACE program following the initial enrollment procedures outlined in 42 CFR 460.152.

**Author:** Linda Lackey, Medicaid Administrator, LTC Project Development Unit.

**Statutory Authority:** State Plan, Attachment 2.2-A, Attachment 3.1-A and Supplement 3; 42 CFR 460 Subpart I.

**History:** New Rule: Filed September 20, 2011.

**560-X-53-.06. Services for Participants.**

(1) Services provided under PACE must include all Medicaid and Medicare services and covered items, as well as any services for each participant determined to be necessary by the Interdisciplinary Team. Provided services must include comprehensive medical, health, and social services for acute and long term care. Services may be provided directly by the PO or by a subcontractor, and must be available 24 hours a day. For guidelines for required services for Medicare and Medicaid Participants, refer to 42 CFR 460, Subpart F.

(2) Enrolled participants must receive their services through the PO. The services are to be provided at the PACE Center, the participant's home, and inpatient facilities. Attendance at a Center is based on the needs and preferences of each participant. A participant may not be discriminated against in receiving services based on race, ethnicity, national origin, religion, sex, age, sexual orientation, mental/physical disability, or source of payment.

(3) A PO must operate at least one PACE center in its service area. The facility is to have sufficient space to ensure routine attendance by participants and to provide adequate services for the participants. If the center does not fulfill these needs, the PO must increase the number of staff and services at the center as needed. If an additional center is needed, it must meet the same requirements as the initial center.

- (4) Services to be provided include, but are not limited to, the following:
- (a) Primary Care, to include physician and nursing services;
  - (b) Hospital Care;
  - (c) Medical Specialty Services;
  - (d) Prescription Drugs;
  - (e) Dentistry;

- (f) Nursing Home Care;
- (g) Personal Care;
- (h) Physical Therapy;
- (i) Adult Day Care;
- (j) Nutritional Counseling;
- (k) Social Services;
- (l) Laboratory and X-Ray Services;
- (m) Transportation.

(5) An emergency care plan for inpatient and outpatient services must be established and maintained by each PO so that emergency care is provided when needed. The plan must ensure that CMS, AMA, and participants are held harmless if the PO does not make payments for the care provided. Emergency care is to be provided when services are needed immediately due to an injury or sudden illness and care cannot be provided timely by the PO or a contract provider, causing risk of permanent damage to the participant's health. Requirements and guidelines for emergency services are located in 42 CFR 460.100.

- (6) Excluded services under the PACE program include:
- (a) Any service, including a required service that has not been authorized by the Interdisciplinary Team, unless it is an emergency service;
  - (b) Private room and private duty nursing services, unless medically necessary, in an inpatient facility;
  - (c) Non-medical items or charges for personal convenience (telephone, radio, television) in an inpatient facility, unless the item(s) have been included as part of the participant's care plan by the Interdisciplinary Team;
  - (d) Cosmetic surgery, unless it is required to improve the function of a malformed part of the body resulting from an accidental injury or for reconstruction following a mastectomy;
  - (e) Experimental medical, surgical, or other health procedures;
  - (f) Services furnished outside of the United States (refer to 42 CFR 460.96 for exceptions).

**Author:** Linda Lackey, Medicaid Administrator, LTC Project Development Unit.

**Statutory Authority:** State Plan, Attachment 2.2-A, Attachment 3.1-A and Supplement 3; 42 CFR 460 Subpart F.

**History:** New Rule: Filed September 20, 2011.

**560-X-53-.07. Participant Assessment & Plan of Care.**

(1) An initial comprehensive assessment and a detailed written plan of care must be established for each participant immediately upon his or her enrollment in the PACE program. The Interdisciplinary Team is responsible for implementing, coordinating, monitoring, and documenting the assessments, reassessments, and the plan of care in the participant's medical records.



(2) The assessment of the participant for the plan of care must be conducted in person by the following members of the Interdisciplinary Team: primary care physician, registered nurse, social worker (Master's level), physical and occupational therapists, recreational therapist or activity coordinator, dietitian, and home care coordinator (42 CFR 460.104). Other members of the Team may be included in the assessment as recommended by the initial members of the Team conducting the assessments. The assessments are to be compiled into a single plan of care once completed. During the assessment, female participants must be informed they can choose a qualified specialist to provide routine and preventive health services for women. The assessment must include documentation on the following:

- (a) Participant's physical and cognitive function and ability, status of health, behavior, and language;
- (b) Medications and treatment needs;
- (c) Participant and caregiver's preferences for services;
- (d) Availability of socialization and family support;
- (e) Nutritional, medical, and dental status;
- (f) Environment of and access in to the home;
- (g) Psychosocial status.

(3) The plan of care must be evaluated every six months to ensure necessary changes in care are made, as well as documenting outcomes of care that were provided during the six-month period. Reassessments may be conducted more often if required by the condition of the participant. Reassessments are to be conducted in person by the primary care physician, registered nurse, social worker (Master's level), recreational therapist or activity coordinator, and other Team members involved in the development and implementation of the plan of care. Annual reassessments are to be conducted in person by the physical therapist, occupational therapist, dietitian, and home care coordinator.

(4) Unscheduled reassessments may be required in addition to scheduled reassessments if there is a change in the health or psychosocial status of a participant, or if the participant or their representative requests that a service be implemented, eliminated, or continued. These assessments must also be conducted in person by the appropriate members of the Team. Detailed procedures regarding requests for the implementation, elimination, or continuation of services are to be in place for timely resolution of the requests. Refer to 42 CFR 460.104 for guidelines regarding the resolution of requests for reassessments by the participant or their representative.

(5) Upon the completed reassessment of the participant, the plan of care must be re-evaluated and any changes must be discussed by the Interdisciplinary Team (IDT). The changes must be approved by the IDT and the participant or their representative. Once approved, the changes must be provided as quickly as required by the participant's health.

**Author:** Linda Lackey, Medicaid Administrator, LTC Project Development Unit.

**Statutory Authority:** State Plan, Attachment 2.2-A, Attachment 3.1-A and Supplement

3; 42 CFR 460.104 and 460.106.

**History:** New Rule: Filed September 2011.

**560-X-53-.08. Participants Rights.**

(1) The Participants Bill of Rights is to be written to promote and protect the rights of participants. Written policies and procedures are to be implemented to ensure that participants, their representatives, and PO staff understand the rights of the participant. Upon enrollment, a participant must be verbally informed of his or her rights and all rules and regulations regarding participation in the PACE program. These must also be provided in writing to the participant.

(2) The participants' rights are to be written in English, as well as in any other language that is prominent in the area covered by the PO. The rights are to be displayed in a prominent location within the center.

(3) At a minimum, the rights for participants are to include the rights specified in 42 CFR 460.112. These rights include, but are not limited to:

- (a) Respect and nondiscrimination;
- (b) Disclosure of information;
- (c) Choice of providers within the PO network;
- (d) Access to emergency services;
- (e) Participation in decisions for treatment;
- (f) Confidentiality and protection of healthcare information;
- (g) Fair and efficient process for resolving complaints and appeals.

(4) The use of physical and/or chemical restraints, as described in 42 CFR 460.114, for a participant must be limited to the most effective and least restrictive restraint available for the safety of the participant or the safety of others. The decision to use restraints must be made by the Interdisciplinary Team. Use of any restraint must meet the conditions listed in §460.114. The participant's condition must be assessed, monitored, and re-evaluated on a continuous basis until the restraints are removed.

(5) Written grievance procedures must be established by the PO to respond to and rectify a written or verbal complaint of a medical or nonmedical violation of a participant's rights. Refer to §460.120 for the requirements of the grievance process to be included in the procedures.

The procedures must be verbally explained and provided in writing to the participant upon enrollment into the PACE program and on an annual basis thereafter. Required services for the participant must continue to be provided during the grievance process

The PO must maintain, aggregate, and analyze information on grievance proceedings for use in their internal quality assessment and performance improvement program.

(6) Written appeal procedures must be established by the PO regarding the non-coverage or non-payment of a service for a participant, including denials of services, reductions in services, and termination of services. Minimum requirements for the appeals procedures are listed in §460.122.

The procedures are to be provided to the participant upon enrollment into the PACE program and on an annual basis thereafter, as well as at the time of any denial or non-payment of a service. All appropriate parties are to be provided written notification of the appeal of a participant and allowed sufficient time present evidence pertaining to the dispute. Guidelines for the continuation of services during the appeal process are provided in §460.122.

A PO must have procedures in place to expedite the appeals process, as specified in §460.122, if a participant believes that his or her life, health, or ability to regain and or maintain maximum function are jeopardized without the service(s) in dispute.

If the outcome of the appeal is in favor of the participant, the disputed service(s) is to be furnished by the PO as quickly as the health condition of the participant determines it is needed. If the outcome of the appeal is not in favor of the participant, in part or in whole, the PO must notify CMS, AMA, and the participant. The participant must also be notified in writing of the appeal rights under Medicare and/or Medicaid. If the participant wishes to appeal at that time, and both entities are applicable, the PO is to assist the participant in choosing which to pursue and is to forward the appeal to the appropriate entity (§460.124).

The PO must maintain, aggregate, and analyze information on grievance proceedings for use in their internal quality assessment and performance improvement program.

**Author:** Linda Lackey, Medicaid Administrator, LTC Project Development Unit.

**Statutory Authority:** State Plan, Attachment 2.2-A, Attachment 3.1-A and Supplement 3; 42 CFR 460 Subpart G.

**History:** New Rule: Filed September 20, 2011.

**560-X-53-.09. Interdisciplinary Team.**

(1) An Interdisciplinary Team, comprised of members as listed in §460.102, is to be established for each PACE center. Participants are to be assigned to the Team located at the center he or she attends upon enrollment for an assessment so that the needs of each participant can be met.

(2) Members of the Team must primarily serve PACE participants and are responsible for the initial assessment, reassessments as required, developing a plan of care, and coordinating the care of a participant. The primary care physician on the Team must furnish primary medical care for each participant, and is responsible for managing a

participant's medical situations, inpatient care, and use of specialists. Each member is responsible for reporting and documenting the medical, functional, and psychosocial condition of each participant to the Team. Written procedures must be established for use by the Team to ensure confidentiality with the participant between Team members and contractors that provide service for the participant.

**Author:** Linda Lackey, Medicaid Administrator, LTC Project Development Unit.

**Statutory Authority:** State Plan, Attachment 2.2-A, Attachment 3.1-A and Supplement 3; 42 CFR 460.102.

**History:** New Rule: Filed September 20, 2011.

**560-X-53-10. PACE Organization Enrollment and Agreement.**

(1) An entity that wishes to become a PO must complete an application that describes how the entity meets all the requirements to be a PO. The application must be submitted to, and approved by, AMA and CMS. AMA will include an assurance with the application sent to CMS that the entity is qualified to be a PO and that AMA is willing to enter into an agreement with the entity. CMS will then evaluate the application based on the information contained in the application, as well as information obtained by onsite visits conducted by CMS and/or AMA.

(2) The proposed service area of the PO must be included in the application. If the proposed area is already serviced by another PO, it may be excluded by CMS and AMA in order to avoid duplication of services and impairing the financial and service viability of an existing PO.

(3) CMS will notify the entity within 90 days from the receipt of the application that the application is approved or denied, or that additional information is required. If the application is denied, the entity will be notified in writing of the reason for the denial and the process for requesting reconsideration by CMS. If additional information is requested, CMS will have an additional 90 days from receipt of the requested information to make a final decision. If CMS fails to make a determination or take any action on the application within 90 days of the receipt of the application or within 90 days of receipt of the additional requested information, the application will be deemed as approved.

(4) An entity, or PO, may submit a request for a waiver of regulatory requirements to meet the needs of the organization or the area it will be servicing. The waiver must be submitted as a separate document and can be submitted with the application. Requirements to the principles listed in 42 CFR 4670.26 will not be waived.

(5) Once an application is approved, an agreement must be signed by the organization, the AMA, and an authorized official of CMS. The agreement is effective for one contract year, but may be extended each year unless any party chooses to terminate the agreement. At a minimum, the agreement must include the information required in 42 CFR 460.32.

**Author:** Linda Lackey, Medicaid Administrator, LTC Project Development Unit.

**Statutory Authority:** State Plan, Attachment 2.2-A, Attachment 3.1-A and Supplement 3; 42 CFR 460 Subpart B and Subpart C.

**History:** New Rule: Filed September 20, 2011.

**560-X-53-11. PACE Organization Administrative Requirements.**

(1) A PO must be (or be a distinct part of) an entity of a city, county, state, or tribal government, or a private not-for-profit entity organized for charitable purposes under section 501(c)(3) of the Internal Revenue Code of 1986.

(2) A Program Director must be employed, or contracted with, to be responsible for the oversight and administration of the PO.

(3) A Medical Director must be employed, or contracted with, to be responsible for the delivery of care for participants, clinical outcomes, and the implementation and oversight of quality assessment and improvement program.

(4) An organizational chart must be established and maintained indicating the officials in the PO and any relationship(s) to other organizational entities. AMA and CMS are to be notified in writing of any organizational changes at least 14 days prior to the effective date of the changes.

(5) An identifiable governing body (e.g., a Board of Directors) must be established with full legal authority and responsibility for the following:

- (a) Governance and operation of the PO;
- (b) Development of policies;
- (c) Management and provision of all services;
- (d) Establishment of personnel policies, participant health and safety policies, and an operational plan to ensure health and safety of participants;
- (e) Fiscal operations;
- (f) Quality assessment and improvement program.

(6) A Participant Advisory Committee, comprised mainly of participants or representatives, must be established to provide advice to the governing body regarding participants' concerns. Requirements for the responsibilities of the Committee are listed in §460.62.

(7) Each member of the PO staff that has direct contact with participants must meet the general qualification requirements listed in §460.64. A staff member must be designated to oversee these activities and to ensure that all staff meet the requirements listed in §460.71.

(8) A PO must not employ or contract with individuals or organizations with criminal convictions as described in 42 CFR 460.68. Members, or immediate family of any member, of the PO's governing body that have a direct or indirect conflict of interest

in supplies or care-related service contracts with the PO must be disclosed. Formal procedures must be in place to address these issues as required in §460.68.

(9) There must be a written contract between the PO and each outside organization, agency, or individual that provides administrative or care-related services not provided to participants by the PO. Each contract must meet the requirements listed in §460.68.

(10) A PACE center must be designed, constructed, equipped, and maintained to ensure the safety of participants, personnel, and visitors. There must be suitable space and equipment to provide primary medical care and serve other functions required by the center. Written procedures must be established and implemented to ensure maintenance of equipment as recommended by the manufacturer. A center must meet all applicable fire safety regulations as outlined in §460.72.

(11) Written procedures must be established and maintained to manage medical and non-medical emergencies and disasters that may threaten the health and safety of participants, personnel, and visitors as described in §460.72.

(12) Written procedures must be established and maintained for an infection control plan to ensure a safe and sanitary environment to prevent and control the transmission of diseases and infections. Requirements for this plan are in §460.74.

(13) Transportation services that are provided must be safe, accessible, and equipped to meet the needs of participants. Vehicles, including those provided by contractors, must be maintained in accordance with the recommendation of the manufacturer and be equipped to communicate with the center. All transportation personnel are to be trained to manage the special needs of participants and emergencies situations. Transportation personnel are to be informed of any pertinent changes in a participant's care by the Interdisciplinary Team.

(14) Nourishing, palatable, and well-balanced meals must be furnished to meet the daily nutritional and special dietary needs of participants and must meet the requirements outlined in §460.78. Foods and dietary supplements must be procured from approved sources. Sanitary conditions must be maintained in the storing, preparation, and serving of foods. Garbage and refuse are to be disposed of properly.

(15) A PO must be fiscally sound and have a documented insolvency plan that has been approved by AMA and CMS. A PO must also have show that it has arrangements to cover expenses in the event it becomes insolvent. Guidelines and requirements for these plans are outlined in §460.80.

**Author:** Linda Lackey, Medicaid Administrator, LTC Project Development Unit.

**Statutory Authority:** State Plan, Attachment 2.2-A, Attachment 3.1-A and Supplement 3; 42 CFR 460 Subpart E.

**History:** New Rule: Filed September 20, 2011.

**560-X-53-.12. PACE Organization Marketing Requirements.**

(1) A written marketing plan that includes measurable enrollment objectives and a tracking system for effectiveness must be established and maintained by the PO.

(2) Information must be provided to the public regarding the PO and the marketing materials must be free of material inaccuracies, misleading information, and misrepresentations. The materials must contain information to assist individuals in making an informed decision regarding enrollment and at a minimum must include the following:

(a) A description of the policies and requirements for enrollment and disenrollment for the PACE program;

(b) Procedures for enrollment;

(c) A description of benefits and services provided;

(d) Information regarding premiums;

(e) Notice that all primary and specialized health care, other than emergency services, must be received through the PO or an entity that has been authorized by the PO;

(f) Notice that if services received are not provided or authorized by the PO, that the participant may be fully and personally liable for the costs incurred.

(3) All marketing information and materials must be approved by CMS before distribution. The initial marketing information is submitted as part of the PACE Organization application and is approved when the application is approved. Any revisions or updates to the material must also be approved by CMS. CMS will approve or disapprove the revisions or updates within 45 days of receipt of the materials. The materials will be deemed approved if CMS and AMA do not notify the PO of disapproval within the 45 day period.

(4) Marketing materials are to be printed in English and in any other primary language(s) of the community, as well as in Braille if necessary.

(5) A PO must ensure that prohibited marketing practices, as described in §460.82, are not used by its employees or agents when distributing marketing information and materials.

**Author:** Linda Lackey, Medicaid Administrator, LTC Project Development Unit.

**Statutory Authority:** State Plan, Attachment 2.2-A, Attachment 3.1-A and Supplement 3; 42 CFR 460.82.

**History:** New Rule: Filed September 20, 2011.

**560-X-53-.13. Quality Assessment and Performance Improvement.**

(1) A written data-driven plan for the Quality Assessment and Performance Improvement Program must be developed, implemented, and maintained by a PO. The

plan must include all services provided by the PO, identify areas for maintaining and improving delivery of services and care, identify development and implementation methods to maintain and improve the quality of care provided, and a plan of action to document and inform appropriate parties of assessment and performance results. Interdisciplinary Team members, PACE staff, and contractors are to be involved in the development and implementation of all activities in the program and made aware of the results of the activities. The plan must be reviewed annually by the governing body of the PO and revisions made as needed.

(2) The Quality Assessment and Performance Improvement Program must include measures that will be used to demonstrate improved performance in the areas described in 460.134. The outcome measures must be based on current clinical practice guidelines and professional practice standards that are applicable to the care of participants in the PACE program. The PO must ensure that all data used is accurate and complete.

(3) The minimum levels of performance for standardized quality measures established by CMS and AMA as specified in the PACE program agreement must be met or exceeded. Areas for improvement should be prioritized based on the severity of the problems identified. Issues that directly or potentially threaten the health and safety of a Participant should be corrected immediately.

(4) A Quality Assessment and Performance Improvement Coordinator must be appointed to oversee the establishment and implementation of the program. Duties of the Coordinator include communication with Participants and caregivers to encourage their participation in the program, including their input regarding their satisfaction with the program.

(5) One or more committees with community input must be established. The duties of the committee(s) include the evaluation of the program's outcome measures and to review the implementation and results of the improvement plan. The committee(s) is to also provide input regarding ethical decision making, including end-of-life issues and implementation of the Patient Self-Determination Act.

(6) External quality assessment and reporting requirements as specified by CMS or AMA in accordance with §460.202 must also be met.

**Author:** Linda Lackey, Medicaid Administrator, LTC Project Development Unit.

**Statutory Authority:** State Plan, Attachment 2.2-A, Attachment 3.1-A and Supplement 3; 42 CFR 460 Subpart H.

**History:** New Rule: Filed September 20, 2011.

#### **560-X-53-.14. Federal and State Monitoring.**

(1) Annual reviews of a PO will be conducted by AMA and CMS to ensure compliance. Onsite visits will be conducted every two years at a minimum. The scope of



the reviews includes, but not limited to, the following:

- (a) Onsite visits, including but not limited to
  1. Review of Participants' charts;
  2. Interviews with staff, contractors, Participants, caregivers;
  3. Observation of program operations (marketing, services, enrollment & disenrollment procedures, grievances, appeals, etc);
- (b) Comprehensive assessment of the PO's fiscal soundness;
- (c) Comprehensive assessment of PO's ability to furnish services to Participants;
- (d) Any other areas determined necessary by AMA and/or CMS.

(2) A PO will be informed of any deficiencies found during a review and must take action necessary to correct the identified deficiencies. Failure by the PO to correct deficiencies may result in sanctions or terminations, as specified in 42 CFR 460 Subpart D. The effectiveness of the corrective actions will be monitored by AMA or CMS.

(3) AMA and CMS will notify the PO of the final results of the review and any recommendations for changes to the program. The results are also made available to the public upon request. Upon receipt of the results and recommendations, the PO must post a notice of the availability of the results and make them readily accessible.

**Author:** Linda Lackey, Medicaid Administrator, LTC Project Development Unit.

**Statutory Authority:** State Plan, Attachment 2.2-A, Attachment 3.1-A and Supplement 3; 42 CFR 460 Subpart K.

**History:** New Rule: Filed September 20, 2011.

**560-X-53-.15. Data Collection, Record Maintenance, Report.**

(1) A PO must collect data, maintain records, and submit reports as specified by AMA and CMS in the PACE agreement to enable monitoring of the operation, cost, quality, and effectiveness of the program and establishment of payment rates.

(2) Written procedures must be established to safeguard all data, records, and financial books against loss, destruction, unauthorized use, or alteration.

(3) All federal and state laws are to be followed regarding the confidentiality and disclosure of health information and records for Participants. Written procedures must be established to ensure that confidentiality is maintained. Records should be updated timely in order to maintain accurate records. Each Participant has the right to review their record and must be allowed timely access to review and copy his or her records. Each Participant may also request amendments to his or her records. Only authorized individuals may receive information or copies of a record. Original medical records are to be released only in accordance with federal and state laws, court orders, or subpoenas.

(4) Records are to be retained as specified in 42 CFR 460.200.

(5) At a minimum, AMA and CMS are to have access to data and records pertaining to participant health outcomes, financial information, medical records, and personnel records.

(a) A health information system must be established and maintained by a PO. The system is to be utilized to collect, analyze, integrate, and report data needed to measure the PO's performance and outcome of care furnished to Participants.

(b) Accurate financial reports are to be prepared using an accrual basis of accounting that can be verified by qualified auditors. Standardized accounting, statistical, and reporting practices and definitions that are widely accepted in the health care industry must be followed. The financial system must accurately document all financial transactions, provide audit trails to source documents, and have the ability to generate financial statements. CMS and AMA must be allowed access to any financial information and records of an original entry that pertain to any aspect of services furnished, reconciliation of benefit liabilities for participants, and determinations of Medicare and Medicaid payments.

(c) Quarterly financial statements are to be submitted by the PO within 45 days of the last day of each quarter during the trial period. Monthly and quarterly statements may be required if CMS and AMA determine that more frequent monitoring is required. A financial statement certified by an independent CPA must be submitted no later than 180 days of the end of the PO's fiscal year. Required contents for the statements are listed in 460.208.

(d) Complete and accurately documented comprehensive medical records are to be maintained for each Participant following accepted professional standards. All entries must be legible, clear, complete, dated, and appropriately authenticated as specified in 460.210 (d). Each medical record must contain the information and documentation specified in 460.210. Medical records are to be systematically organized, readily accessible, available to all staff, and maintained at the PO where services are received by the Participant. A copy of medical information must be transferred promptly between treatment facilities as needed.

**Author:** Linda Lackey, Medicaid Administrator, LTC Project Development Unit.

**Statutory Authority:** State Plan, Attachment 2.2-A, Attachment 3.1-A and Supplement 3; 42 CFR 460 Subpart L.

**History:** New Rule: Filed September 20, 2011.

**560-X-53-.16. Medicaid and Medicare Payments, and Participant Premiums.**

(1) AMA will make a monthly capitation payment to a PO for each Medicaid participant enrolled in the program and will be generated by the Medicaid Management Information System (MMIS). The monthly capitation payment will be a fixed amount, regardless of changes in a participant's health or placement into a nursing facility, and will be specified in the agreement. The amount paid will be less than the amount that would be paid if a participant were not enrolled in the PACE program. The capitation payment must be accepted in full for Medicaid participants. The PO may not bill, charge, collect, or receive any other form of payment for the participant unless based on the

exceptions listed in §460.182(c).

(2) CMS will make a monthly capitation payment to the PO for each participant eligible for Medicare. This payment is an all-inclusive payment for Medicare benefits provided to participants. Guidelines for Medicare payments are in §460.180.

(3) A participant cannot be charged a premium if he or she is eligible for Medicaid and Medicare, or for Medicaid only. The premium amount a PO can charge must meet the guidelines in §460.186.

**Author:** Linda Lackey, Medicaid Administrator, LTC Project Development Unit.

**Statutory Authority:** State Plan, Attachment 2.2-A, Attachment 3.1-A and Supplement 3; 42 CFR 460 Subpart J.

**History:** New Rule: Filed September 20, 2011.

#### **560-X-53-17. Sanctions and Enforcement Actions.**

(1) Penalties and sanctions may be imposed by CMS for a PO if it is determined that the PO has committed any of the violations listed in §460.40. Penalties and/or sanction will be imposed in addition to any other remedies authorized by law.

(2) CMS may also elect to suspend the enrollment of Medicare beneficiaries. CMS may also suspend Medicare payments to the PO or deny payment to AMA for medical assistance for services provided under the PACE agreement. Limitations for civil monetary penalties are addressed in §460.46. The penalties and sanctions imposed will be effective until CMS determines the cause of the violation has been corrected or the violation will not likely recur.

(3) As specified in §460.48, if CMS or AMA determine that a PO is not in compliance, one or more of the following actions will be taken:

- (a) Condition the continuation of the PACE agreement upon timely execution of a corrective action plan,
- (b) Withhold some or all payments under the PACE agreement until the deficiency is corrected,
- (c) Terminate the PACE agreement.

**Author:** Linda Lackey, Medicaid Administrator, LTC Project Development Unit.

**Statutory Authority:** State Plan, Attachment 2.2-A, Attachment 3.1-A and Supplement 3; 42 CFR 460 Subpart D.

**History:** New Rule: Filed September 20, 2011.

#### **560-X-53-18. Termination of a PACE Program Agreement.**

(1) CMS or AMA may terminate a PO agreement at anytime for cause due to, but not limited to, circumstances listed in §460.50 (b) and (c).

(2) If CMS or AMA terminates a PO agreement, the PO will first be provided a reasonable opportunity to develop and implement a corrective action plan to rectify the reason(s) for the termination. The PO will also be provided a reasonable notice and opportunity for a hearing, including the right to appeal an initial determination, before the agreement is terminated. An agreement may be terminated immediately if it is determined that the health and safety of the Participants are at risk due to the reason(s) for the termination of the agreement.

(3) A PO may terminate an agreement after timely notice to CMS, AMA, and Participants. A 90-day notice must be provided to CMS and AMA. A 60-day notice must be provided to Participants.

(4) A detailed written plan describing actions to be taken for the termination must be developed by the PO. The actions must include written notice to CMS, AMA, Participants, and the community informing them of the termination of the agreement and transition procedures. The PO must assist Participants in obtaining necessary transitional care through referrals and make medical records available to the new providers. Assistance is to be given to Participants for reinstatement of Medicaid and Medicare benefits as applicable. The plan must also include information regarding the termination of marketing and enrollment activities.

**Author:** Linda Lackey, Medicaid Administrator, LTC Project Development Unit.

**Statutory Authority:** State Plan, Attachment 2.2-A, Attachment 3.1-A and Supplement 3; 42 CFR 460 Subpart D.

**History:** New Rule: Filed September 20, 2011.