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To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.

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1.0 Description of the Procedure, Product, or Service

The Program of All-Inclusive Care for the Elderly (PACE) is a unique model of managed care service delivery for the frail elderly living in the community. Most PACE participants are dually eligible for Medicare and Medicaid benefits, and all are certified eligible for nursing facility level of care according to the standards established by the state Medicaid agency.

The PACE program uses monthly capitated payments from Medicare and NC Medicaid (Medicaid) to provide an integrated and comprehensive medical and social service delivery system for elderly individuals who choose to receive services in the least restrictive community-based setting of care. PACE uses an interdisciplinary team to provide services at the PACE Center and to case manage the services and supports provided to PACE participants by providers in the PACE network.

The PACE program is located in the community and contains a certified adult day health program. Services are provided on site and supplemented by in-home and referral to other services according to each participant's needs.

1.1 Definitions

State Administering Agency means the same as found under 42 CFR 460.6, Definitions.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(*The term "General" found throughout this policy applies to all Medicaid and NCHC policies*)

a. An eligible beneficiary shall be enrolled in either:
   1. the NC Medicaid Program *(Medicaid is NC Medicaid program, unless context clearly indicates otherwise*); or
   2. the NC Health Choice (*NCHC is NC Health Choice program, unless context clearly indicates otherwise)* Program on the date of service and shall meet the criteria in **Section 3.0 of this policy**.

b. Provider(s) shall verify each Medicaid or NCHC beneficiary's eligibility each time a service is rendered.

c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

2.1.2 Specific

(***The term "Specific" found throughout this policy only applies to this policy***)

a. Medicaid

The individual shall meet the eligibility requirements under 42 CFR §460.150 Eligibility to enroll in a PACE program.

b. NCHC

NCHC beneficiaries are not eligible for Program of All-Inclusive Care for the Elderly (PACE).

2.1.3 Financial Eligibility

To qualify for PACE, an individual shall meet financial eligibility requirements for Long-Term Care Medicaid/PACE established by NC Medicaid.

2.2 Special Provisions

2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. **42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]**

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets

all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

b. **EPSDT and Prior Approval Requirements**

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide,* and on the EPSDT provider page. The Web addresses are specified below.

   NCTracks Provider Claims and Billing Assistance Guide: https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

   EPSDT provider page: https://medicaid.ncdhhs.gov/

   NOTE: EPSDT does not apply to Program of All-Inclusive Care for the Elderly (PACE).

2.2.2 EPSDT does not apply to NCHC beneficiaries

2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age

NC Medicaid shall deny the claim for coverage for an NCHC beneficiary who does not meet the criteria within **Section 3.0** of this policy. Only services included under the NCHC State Plan and the NC Medicaid clinical coverage policies, service definitions, or billing codes are covered for an NCHC beneficiary.

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

3.1 General Criteria Covered

Medicaid and NCHC shall cover the procedure, product, or service related to this policy when medically necessary, and:

a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs;
b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and
c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary's caretaker, or the provider.

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3.2 Specific Criteria Covered

3.2.1 Specific criteria covered by both Medicaid and NCHC

None Apply.

3.2.2 Medicaid Additional Criteria Covered

Medicaid shall cover medically necessary PACE services for a Medicaid participant when:

a. documented in the person-centered plan of care,
b. the individual meets Medicaid's requirements for nursing facility level of care, as determined by Medicaid's level of care screening tool (refer to **Subsection 5.5**);
c. the level of care determination is confirmed by an initial comprehensive assessment conducted by the PACE organization (refer to **Subsection 5.6**); and
d. the participant meets the requirements indicated in **Subsection 2.0.**

3.2.3 NCHC Additional Criteria Covered

None Apply**.**

3.2.4 Continuation of Service in the Absence of Criteria

A PACE participant may be deemed eligible if, following enrollment, the participant no longer meets nursing facility level of care criteria; but the State determines, in accordance with applicable regulations, that the absence of PACE program services would result in a deterioration of the individual's health status to the point where the individual would again qualify for PACE within a six-month period following disenrollment.

4.0 When the Procedure, Product, or Service Is Not Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

4.1 General Criteria Not Covered

Medicaid and NCHC shall not cover the procedure, product, or service related to this policy when:

a. the beneficiary does not meet the eligibility requirements listed in **Section 2.0;**
b. the beneficiary does not meet the criteria listed in **Section 3.0;**
c. the procedure, product, or service duplicates another provider's procedure, product, or service; or
d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

4.2 Specific Criteria Not Covered

4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC

None Apply.

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4.2.2 Medicaid Additional Criteria Not Covered

In addition to the specific criteria not covered in **Subsection 4.2.1** of this policy**,** Medicaid shall not cover a monthly capitation fee to the PACE organization when the participant does not meet the criteria in **Subsection 3.2**.

Medicaid shall not cover a monthly capitation fee to the PACE organization when the participant is receiving optional benefits from a 1915 (c) Home and Community-Based Waiver, or Hospice benefit.

4.2.3 NCHC Additional Criteria Not Covered

a. None Apply
b. NCGS § 108A-70.21(b) "Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:
    1. No services for long-term care.
    2. No nonemergency medical transportation.
    3. No EPSDT.
    4. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection."

5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

5.1 Prior Approval

Medicaid shall require prior approval for PACE enrollment. The need for nursing facility level of care must be confirmed by the DHHS fiscal contractor's level of care review and the PACE organization's assessment as described in **Subsection 5.6.**

5.2 Enrollment Requirements

5.2.1 Enrollment Agreement

When the participant meets the eligibility requirements and wants to enroll, he or she shall sign an enrollment agreement that contains the minimal information under 42 CFR 460.154.

5.2.2 Enrollment Documentation

The PACE organization shall give a participant, upon signing the enrollment agreement, all of the information according to 42 CFR 460.156.

5.2.3 Effective Date of Enrollment

According to 42 CFR 460.158, the effective date of the participant's enrollment is the first day of the calendar month following the date the PACE organization receives the signed Enrollment Agreement.

5.2.4 Continuation of Enrollment

According to 42 CFR 460.160, the PACE enrollment continues until the

participant's death, regardless of changes in health status, unless the participant voluntarily disenrolls in accordance with 42 CFR 460.162, or is involuntarily disenrolled in accordance with 42 CFR 460.164.

5.3 Sole Source of Services

As indicated in 42 CFR 460.154(p), each individual enrolling in PACE shall accept PACE as his or her sole source for services. This requirement must be included in the PACE Enrollment Agreement and the individual or legally responsible person shall acknowledge acceptance of this requirement by signing a form approved by the (SAA).

5.4 Participant Disenrollment from PACE

5.4.1 Voluntary Disenrollment

According to 42 CFR 460.162, a PACE participant may request to voluntarily disenroll from PACE at any time without cause.

A participant's voluntary disenrollment is effective on the first day of the month following the date the PO receives the participant's notice of voluntary disenrollment.

A PACE organization must ensure that its employees or contractors do not engage in any practice that would reasonably be expected to have the effect of steering or encouraging disenrollment of participants due to a change in health status.

The PACE organization shall assist the individual in obtaining other care and services to meet his or her medical, functional, psychological, social and personal care needs. The PACE organization shall submit to the SAA the transition plan of care.

~~**Note**: The disenrollment date will not be effective until the participant is appropriately reinstated into other Medicaid programs and alternative services are arranged.~~

5.4.2 Involuntary Disenrollment

A participant's involuntary disenrollment occurs after the PACE organization meets the requirements set forth in this section and is effective on the first day of the next month that begins 30 days after the day the PACE organization sends notice of the disenrollment to the participant.

A PACE participant may be involuntarily disenrolled for any of the following reasons in accordance with 42 CFR 460.164:

a. Failure to Pay: Any participant who fails to pay, or make satisfactory arrangements to pay any premiums due, to the PACE organization after a thirty-day grace period;

Note: 42 CFR§460.170 Reinstatement in PACE. (b), "If the reason for disenrollment is failure to pay the premium and the participant pays the premium before the effective date of disenrollment, the participant is reinstated in the PACE program with no break in coverage".

b. Any participant who after a 30-day grace period, fails to pay or make satisfactory arrangements to pay any applicable Medicaid spend down liability or any amount due under post-eligibility treatment of income process as permitted under 42CFR 460.182 and 460.184.

c. Disruptive or Threatening Behavior: A participant engages in documented disruptive or threatening behavior. The participant exhibits either of the following:
   1. behavior that jeopardizes his or her health or safety, or the safety of others;-or
   2. consistent refusal to comply with an individual plan of care or the terms of the PACE enrollment agreement by a participant with decision-making capacity.

   Noncompliant behavior includes:
   1. Repeated noncompliance with medical advice; or
   2. Repeated failure to keep appointments.

   A participant's caregiver who engages in disruptive or threatening behavior that jeopardizes the participant's health or safety , or the safety of the caregiver or others.

   Note: A PACE organization may not involuntarily disenroll a PACE participant on the grounds that the participant has engaged in noncompliant behavior related to an existing mental or physical condition unless the participant's behavior is jeopardizing his or her health or safety or that of others.

d. Relocation Outside of the Service Area: The participant moves out of the PACE program service area or is out of the service area for more than 30 consecutive days without PACE organization concurrence;

e. The participant is determined to no longer meet the State Medicaid nursing facility level of care requirements and is not deemed eligible.

f. Non-renewal or Termination of Program Agreement: The PACE organization's program agreement with the Centers for Medicare & Medicaid Services (CMS) and the SAA is not renewed or terminated.

g. The PACE organization is unable to offer health care services due to the loss of State licenses or contracts with outside providers

5.4.3 Procedures for Involuntary Disenrollment

~~a. The PACE organization shall comply with 42 CFR 460.164(a)(1)(2)(3)(4)(5)(6) as follows:~~

~~"Reasons for involuntary disenrollment. A participant may be involuntarily disenrolled for any of the following reasons:~~

~~1. The participant fails to pay, or to make satisfactory arrangements to pay, any premium due the PACE organization after a 30-day grace period.~~

~~2. The participant engages in disruptive or threatening behavior, as described in 42 CFR 460.164 (c) (1)(i,ii) and 42 CFR 460.104 (c) (2)paragraph (b) of this section~~

3. ~~The participant moves out of the PACE program service area or is out of the service area for more than 30 consecutive days, unless the PACE organization agrees to a longer absence due to extenuating circumstances.~~
4. ~~The participant is determined to no longer meet the State Medicaid nursing facility level of care requirements and is not deemed eligible.~~
5. ~~The PACE program agreement with CMS and the State administering agency is not renewed or is terminated.~~
6. ~~The PACE organization is unable to offer health care services due to the loss of State licenses or contracts with outside providers".~~

~~**Note:** In addition to the above reasons, a PACE organization may have a waiver allowing for involuntary disenrollment for additional reasons such as, disruptive or threatening behavior by a family member or failure of Medicaid participants to pay share of cost.~~

Before an involuntary disenrollment is effective, the State administering agency must review it and determine in a timely manner that the PACE organization has adequately documented acceptable grounds for disenrollment.

b. SAA shall require the PACE organization to submit the following requirements before the initiation of an involuntary disenrollment:
   1. health record documentation and information about the circumstances that are the cause of the decision to pursue involuntary disenrollment from a PACE organization; and
   2. steps taken to correct the situation.

   "State administering agency review and final determination. Before an involuntary disenrollment is effective, the State administering agency must review it and determine in a timely manner that the PACE organization has adequately documented acceptable grounds for disenrollment" (42 CFR 460.164(e).

   The PACE organization shall assist the individual in obtaining other care and services to meet his or her medical, functional, psychological, social, and personal care needs. The PACE organization shall submit to the SAA the transition plan of care.

5.4.4 ~~Effective Date of Disenrollment~~ Disenrollment Responsibilities

The PACE organization shall comply with 42 CFR §460.166 Effective date of disenrollment as follows:

a. In disenrolling a participant, the PACE organization must take the following actions:
   1. Use the most expedient process allowed under Medicare and Medicaid procedures, as set forth in the PACE program agreement.
   2. Coordinate the disenrollment date between Medicare and Medicaid (for a participant who is eligible for both Medicare and Medicaid).
   3. Give reasonable advance notice to the participant.

b. Until the date enrollment is terminated, the following requirements must be met:
   1. PACE participants must continue to use PACE organization services and remain liable for any premiums.
   2. The PACE organization must continue to furnish all needed services.

~~In addition to the above, SAA shall require the disenrollment date must not become effective until the participant is appropriately reinstated into other Medicare and Medicaid programs and alternative services are arranged~~.
The PACE organization must do the following:

a. Make appropriate referrals and ensure medical records are made available to new providers within 30 days.
b. Work with CMS and SAA to reinstate the participant in other Medicare and Medicaid programs for which the participant is eligible.

5.5 Nursing Facility Level of Care Review

5.5.1 Initial Level of Care Review

In accordance with 42 CFR 460.152(a)(3), prior to enrollment in PACE, Medicaid shall certify that the PACE applicant meets the state's nursing facility level of care criteria.

5.5.2 Annual Level of Care Review

The PACE organization shall submit the level of care screening tool each calendar year to verify that the enrollee continues to meet nursing facility level of care requirements.

5.6 Assessments

5.6.1 ~~Physical, Functional, and Psychosocial Assessment~~ Initial Comprehensive Assessment

Following certification by the DHHS fiscal contractor that an eligible beneficiary meets nursing facility level of care requirements, the PACE interdisciplinary team (IDT), must conduct an initial in-person comprehensive assessment on each participant. The initial comprehensive assessment must include at a minimum the elements noted in 42CFR 460.104.~~under the direction of the PACE medical director shall comply with 42 CFR 460.104.~~ The assessment must be completed in a timely manner in order to meet the requirements in 42 CFR 460.104 paragraph (b).

As part of the initial comprehensive assessment, each of the following members of the IDT must evaluate the participant in person and develop a discipline-specific assessment of the participant's health and social status:

a. Primary care provider;
b. Registered nurse;
c. Master's-level social worker;
d. Physical therapist;
e. Occupational therapist;
f. Recreational therapist or activity coordinator;

g. Dietitian; and
h. Home care coordinator.

Note: At the recommendation of the IDT, other professional disciplines may be included in the initial comprehensive assessment process.

Within 30 days calendar of the date of enrollment, the IDT must consolidate discipline-specific assessments into a single plan of care for each participant through team discussions and consensus of the entire interdisciplinary team. In developing the plan of care if the interdisciplinary team determines that certain services are not necessary to the care of a participant, the reasoning behind this determination must be documented in the plan of care.

Female participants must be informed that they are entitled to choose a qualified specialist for women's health services from the PACE organization's network to furnish routine or preventive women's health services.

5.6.2 Plan of Care

5.6.2.1 Basic requirement.

Within 30 days of the date of enrollment, the interdisciplinary team members specified in §460.104(a)(2) must develop a comprehensive plan of care for each participant based on the initial comprehensive assessment findings.

a. Content of plan of care. The plan of care must meet the following requirements:

1. Specify the care needed to meet the participant's medical, physical, emotional, and social needs, as identified in the initial comprehensive assessment.
2. Identify measurable outcomes to be achieved.
3. Utilize the most appropriate interventions for each care need that advances the participant toward a measurable goal and outcome.
4. Identify each intervention and how it shall be implemented.
5. Identify how each intervention shall be evaluated to determine progress in reaching specified goals and desired outcomes.

b. Implementation of the plan of care. (1) The team must implement, coordinate, and monitor the plan of care whether the services are furnished by PACE employees or contractors.
c. The team must continuously monitor the participant's health and psychosocial status, as well as the effectiveness of the plan of care, through the provision of services, informal observation, input from participants or caregivers, and communications among members of the interdisciplinary team and other providers.
d. Evaluation of plan of care. On at least a semi-annual basis, the interdisciplinary team must reevaluate the plan of care, including defined outcomes, and make changes as necessary.

e. Participant and caregiver involvement in plan of care. The team must develop, review, and reevaluate the plan of care in collaboration with the participant or caregiver, or both, to ensure that there is agreement with the plan of care and that the participant's concerns are addressed.

f. Documentation. The team must document the plan of care, and any changes made to it, in the participant's medical record.

~~**Note:**~~ The PACE organization shall submit the completed ~~assessment~~ Plan of Care to the SAA for review within ~~30~~ 45 ~~calendar~~ days following enrollment.

5.6.3 Semi-annual reassessment

On at least a semi-annual basis, or more often if a participant's condition dictates, the following members of the interdisciplinary team must conduct an in-person reassessment:

a. Primary care provider.
b. Registered nurse.
c. Master's-level social worker.
d. Other team members that the primary care provider, registered nurse and Master's-level social worker determine are actively involved in the development or implementation of the participant's plan of care.

5.6.4 Unscheduled reassessments.

In addition to semi-annual reassessments, unscheduled reassessments may be required based on the following:

a. *A change in participant status.* If the health or psychosocial status of a participant changes, an in-person reassessment must be conducted by the following interdisciplinary team members:

1. Primary care provider
2. Registered nurse
3. Master's level social worker
4. Other team members that the primary care provider, registered nurse and Master's level social worker determine are actively involved in the development or implementation of the participant's plan of care.

b. *In response to a service determination request.* In accordance with §460.121(h), the PACE organization must conduct an in-person reassessment if it expects to deny or partially deny a service determination request and may conduct reassessments as determined necessary for approved services.

5.6.5 Health and Safety Assessment

The primary consideration underlying the provision of services and assistance to this state's frail and elderly is their desire to reside in a community setting. However, enrollment in a Program of All-Inclusive Care for the Elderly may be denied based upon the inability of the program to ensure the health, safety, and well-being of the individual under any of the following circumstances, based on

assessment of the individual's mental, psychosocial and physical condition and functional capabilities:

a. the individual is considered to be unsafe when left alone, with or without a Personal Emergency Response System;
b. the individual lacks the support of a willing and capable caregiver to ~~who must~~ provide adequate care to ensure the health, safety, and well-being of the individual during any hours when PACE services are not being provided;
c. the individual's needs cannot be supported by the system of PACE services that is currently available;
d. the individual's residence is not reasonably considered to be habitable; ~~or~~
e. the individual's residence or residential environment is unsafe to the extent that it would reasonably be expected to endanger the health and safety of the individual, the individual's caregivers, or the PACE Organizations staff if PACE services are to be provided in the residence;
f. the individual's behavior is disruptive or threatening or is otherwise harmful (e.g. suicidal, injurious to self ~~or others,~~ or destructive of environment); or
g. there is a high risk or an existing condition of abuse, neglect, or exploitation as evidenced by an assessment.

The Health and Safety assessment should be completed prior to enrollment and annually thereafter.

The PACE program shall conduct a comprehensive health and safety assessment to ensure that the applicant's health, safety, or welfare will not be jeopardized by living in the community. The PACE program shall submit the results of the health and safety assessment to the SAA. The SAA shall have up to 5 business days to review and make a determination on this assessment. The assessment must consist of the following:

a. An on-site evaluation of the applicant's residence;
b. An evaluation of the applicant's social support system, including the willingness and capabilities of ~~all~~ informal caregivers; and
c. An evaluation of whether the applicant can be safely transported ~~to the PACE Center.~~

5.7 Person-Centered Plan of Care

Following the required assessments, the PACE program shall develop a plan of care based on the input from the appropriate interdisciplinary team members. The plan of care shall utilize the most appropriate interventions for each care need that advances the participant toward a measurable goal and outcome. Each intervention must be identified with a description of how it will be implemented as well as how each intervention will be evaluated to determine an individual's progress in reaching the specified goals and desired outcomes. The plan of care must also include the beneficiary's signature in an Electronic Health Record (EHR) or on a form approved by the SAA and submit it to the state for approval within 45 calendar days. As required by 42 CFR 460.106 (d), the plan of care must be updated ~~and submitted to the state for approval~~ at least semi-annually.

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5.8 Benefit Package

The PACE benefit package for all participants, regardless of the source of payment, must include items and services as indicated under 42 CFR 460.90, 42 CFR 460.92(a)(b) and 42 CFR 460.94.

5.9 In-Home and Referral Services

As required by 42 CFR 460.98(b), the PACE program must arrange for all in-home and referral services that may be required for each participant. In-home and referral services delivered through a PACE Organization must have a home care agency license under 10A NCAC 13J or by community providers under contract with the PACE program in the manner as set forth in 42 CFR 460.70 and in compliance with 460.71. An individual licensed by the North Carolina Board of Nursing (NCBON) as a Registered Nurse shall provide supervision of the Nurse Aide as under 10A NCAC 13J.1110. The Nurse Aide providing direct care shall be registered as a Nurse Aide I or Nurse Aide II with the Division of Health Services Regulation (DHSR) and the NCBON. The PACE organization shall assure that all participants have freedom of choice in the selection of in-home and referral services within their network.

5.10 Emergency Care Services

The PACE ~~program~~ organization must provide emergency care services in accordance with 42 CFR 460.100.

5.10.1 Emergency Services Care Plan

The PACE ~~program~~ organization shall establish and maintain a written plan to handle emergency care at the PACE Center and when the PACE participant is not at the PACE Center. The plan shall document include procedures to access emergency care both in and out of the PACE Service Area. The PACE ~~program~~ organization shall ensure that participants and caregivers know when and how to access emergency care services when not at the PACE Center and that no prior authorization is required.

5.10.2 Access to Emergency Care

In the case of an emergency medical condition, the PACE participant has the right to access the closest and most readily accessible qualified provider, in or out of the PACE service area, including hospital emergency room services and 911.

5.10.3 Out-of-Service-Area Emergency Care

Medicaid shall not require prior authorization for emergency care covered by the PACE ~~program~~ organization while the PACE participant is out of the service area.

5.10.4 Out-of-Service-Area Follow-up Care

Medicaid shall require prior authorization by the PACE ~~program~~ organization for urgent care and care furnished to the PACE participant to stabilize his or her emergency medical condition that is provided outside the PACE service area.

5.10.5 Retrospective Reviews of Emergency Care

Evaluation of the participant's decision to use emergency services must be based on the prudent layperson standard and no higher standard may be adopted by the PACE ~~program~~ organization.

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6.0 Provider(s) Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

a. meet Medicaid or NCHC qualifications for participation;

b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement;

c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

6.1 PACE Regulations

The PACE program shall comply at all times with the federal PACE regulations specified in 42 CFR Part 460; Programs of All-Inclusive Care for the Elderly (PACE).

6.2 Certification Requirements

As required by N.C. G.S 131D-6 and 10A NCAC 06S, the PACE Center shall be certified as an adult day health program by the North Carolina Division of Aging and Adult Services.

7.0 Additional Requirements

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

7.1 Compliance

Provider(s) shall comply with the following in effect at the time the service is rendered:

a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and

b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s);

c. Upload all appeal related documentation to the Public Consulting Group (PCG) clearinghouse. This documentation includes all adverse decision notices, internal first (1st) level reconsideration review decisions, and formal hearing requests. This uploading requirement also applies to involuntary disenrollment decisions.

d. A PACE organization must adopt and implement effective compliance oversight requirements as required by 42CFR 460.63, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements, as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance oversight program must, at a minimum, include establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with CMS requirements. If the PACE organization discovers evidence of misconduct

related to payment or delivery of items or services, it must conduct a timely, reasonable inquiry into that conduct. The PACE organization must conduct appropriate corrective actions in response to the potential violation. The PACE organization must have procedures to voluntarily self-report potential fraud or misconduct related to the PACE program to CMS and the State administering agency.

7.2 Reports to the State administering agency

Sections 1894 and 1934 of the Social Security Act (the Act) allow states to impose additional requirements on PACE programs. As such, the SAA requires PACE programs to provide copies of all participant Physical, Functional, and Psychosocial Assessments, and initial and annual Health and Safety Assessments, and other reports and documents as may be appropriate to the SAA on a form or in a format approved by the SAA.

CMS and the State administering agency must be able to obtain, examine or retrieve the information specified at 42 CFR 460.200(b)(1), which may include reviewing information at the PACE site or remotely. PACE organizations may also be required to upload or electronically transmit information, or send hard copies of required information by mail.

A PACE organization must submit to CMS and the State administering agency all reports that CMS and the State administering agency require to monitor the operation, cost, quality, and effectiveness of the program and establish payment rates.

7.3 Provision of Service

7.3.1 Service Area

As required by 42 CFR 460.32(a)(1), the PACE program must define its service area. The service area must be approved by the SAA and CMS. The SAA and CMS shall require prior approval for any changes to the service area.

7.3.2 PACE Center

As defined by 42 CFR 460.98~~(d)(1)~~ (c) (1-7), the PACE ~~program~~ organization shall establish a PACE Center that ~~includes~~ provides at a minimum the following services: ~~an adult day health center, a primary care clinic, areas for therapeutic recreation, restorative therapies, socialization, personal care, and dining, which serve as the focal point for coordination and provision of most PACE services~~.

a. Primary care, including services furnished by a primary care provider as defined in §460.102(c) and nursing services.
b. Social services.
c. Restorative therapies, including physical therapy and occupational therapy.
d. Personal care and supportive services.
e. Nutritional counseling.
f. Recreational therapy.
g. Meals.

The PACE organization must operate at least one PACE center either in, or contiguous to, its defined service area with sufficient capacity to allow routine attendance by participants.

The PACE organization must ensure accessible and adequate services to meet the needs of its participants. If necessary, a PACE organization must increase the number of PACE centers, staff, or other PACE services.

If a PACE organization operates more than one PACE center, each PACE center must offer the full range of services and have sufficient staff to meet the needs of participants.

As outlined in 42 CFR 460.98 (e), The frequency of the participant's attendance at the PACE center is determined by the interdisciplinary team, based on the needs and preferences of each participant.

7.3.3 Interdisciplinary Care and Case Management

The PACE program shall establish an interdisciplinary team (IDT) to provide care and case manage all of the services provided or arranged by the PACE program for each participant. The IDT must be composed of at least the following members:

a. Primary care ~~physician~~ provider;
b. Registered Nurse;
c. Master's-level social worker;
d. Physical therapist;
e. Occupational therapist;
f. Recreational therapist or activity coordinator;
g. Dietitian;
h. PACE ~~Center~~ center manager;
i. Home care coordinator;
j. Personal care attendant or his or her representative; ~~and~~
k. Driver or his or her representative.

Per 42 CFR 460.102, One individual may fill two separate roles on the interdisciplinary team where the individual meets applicable state licensure requirements and is qualified to fill the two roles and able to provide appropriate care to meet the needs of participants.

The Primary care provider is responsible for the primary medical care furnished to the participant and may be either a:

a. Primary care physician;
b. A community-based physician; or
c. A physician assistant or a nurse practitioner who is licensed in the State of NC and practices within his or her scope of practice as defined by NC laws with regard to oversight, practice authority and prescriptive authority.

Each primary care provider is responsible for managing a participant's medical

situation as well as overseeing a participant's use of medical specialists and inpatient care.

The PACE organization must ensure that all members of the interdisciplinary team have appropriate licenses or certifications under State law, act within the scope of practice as defined by State laws, and meet the requirements set forth in 42 CFR 460.71.

The PACE organization must establish, implement, and maintain documented internal procedures governing the exchange of information between team members, contractors and participants and their caregivers consistent with the requirements for confidentiality in 42 CFR 460.200(e).

~~7.4 Quality Assessment and Performance Improvement Program~~ Quality Improvement

The PACE program shall develop, implement, maintain, and evaluate an effective data-driven quality ~~assessment and performance~~ improvement ~~(QAPI~~ program, with the minimum requirements according to 42 CFR 460.130, 460.134, 460.136, 460.138.

A PACE organization must meet external quality assessment and reporting requirements, as specified by CMS or the State administering agency, in accordance with §460.202.

In accordance with 42 CFR 460.132, A PACE organization must have a written quality improvement plan that is collaborative and interdisciplinary in nature.

The PACE governing body must review the plan annually and revise it, if necessary.

At a minimum, the plan must specify how the PACE organization proposes to meet the following requirements:

a. Identify areas to improve or maintain the delivery of services and beneficiary care.
b. Develop and implement plans of action to improve or maintain quality of care.
c. Document and disseminate to PACE staff and contractors the results from the quality improvement activities.

7.5 Medical Record Documentation

The PACE organization shall maintain a single comprehensive medical record for each participant. This health record must be made accessible to the SAA upon request within two (2) business days. The health record ~~shall contain the following:~~ for each participant must meet the following requirements as required in 42CFR 460.210(a):

a. Be complete;
b. Accurately documented;
c. Readily accessible;
d. Systematically organized;
e. Available to all staff; and
f. Maintained and housed at the PACE center where the participant receives

services

At a minimum, the medical record shall contain the following:

a. Appropriate identifying information; and
b. Documentation of all services furnished, reporting the following:
   - A summary of emergency care and other inpatient or long-term care services;
   - Services furnished by employees of the PACE Center;
   - Services furnished by contractors and their reports;
c. Interdisciplinary assessments, reassessments, plans of care, treatment, and progress notes documenting the participant's response to treatment;
d. All recommendations for services made by employees or contractors of the PACE organization, including specialists.
e. If a service recommended by an employee or contractor of the PACE organization, including a specialist, is not approved or provided, the reason(s) for not approving or providing that service.
f. Original documentation, or an unaltered electronic copy, of any written communication the PACE organization receives relating to the care, health or safety of a participant, in any format (for example, emails, faxes, letters, etc.) and including, but not limited to the following:
   1. Communications from the participant, his or her designated representative, a family member, a caregiver, or any other individual who provides information pertinent to a participant's health or safety or both.
   2. Communications from an advocacy or governmental agency such as Adult Protective Services.
g. Laboratory, radiological and other test reports;
h. Medication records;
i. Hospital discharge summaries, if applicable;
j. Reports of contact with informal support (such as the caregiver, legal guardian, or next of kin);
k. Enrollment Agreement;
l. Physician orders;
m. Discharge summary and disenrollment justification, if applicable;
n. Advance directives, if applicable;
o. A signed release permitting disclosure of personal information.

7.6 Medical Record Retention

According to 42 CFR 460.200, health records must be maintained in an accessible location for at least ~~six (6)~~ ten (10) years after the last entry date or ~~six (6)~~ ten (10) years after the date of disenrollment.

Note: If litigation, a claim, a financial management review, or an audit arising from the operation of the PACE program is started before the expiration of the retention period, the PACE organization must retain the records until the completion of the litigation or resolution of the claims or audit findings.

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7.7 Additional appeal rights under Medicare or Medicaid

According to 42 CFR 460.122, The PACE organization must have a formal written appeals process, with specified timeframes for response, to address noncoverage or nonpayment of a service. An appeal is a participant's action taken with respect to the PACE organization's noncoverage of, or nonpayment for, a service including denials, reductions, or termination of services.

A PACE organization must inform a participant in writing of his or her appeal rights under Medicare or Medicaid managed care, or both, assist the participant in choosing which to pursue if both are applicable, and forward the appeal to the appropriate external entity.

Appeal rights under Medicaid. Medicaid participants have the right to a State Fair Hearing as described in 42 CFR 460.124 (b).

Appeal rights for dual eligible participants. Participants who are eligible for both Medicare and Medicaid have the right to external review by means of either the Independent Review Entity described in 42 CFR 460.124 (a) or the State Fair Hearing process described in 42 CFR 460.124 (b).

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8.0 Policy Implementation/Revision Information

Original Effective Date: February 1, 2008

Revision Information:

Date	Section Revised	Change
7/1/11	Section 1.0	Updated standard DMA policy template language and revised language related to LOC determination
7/1/11	Section 2.0	Updated standard DMA policy template language
7/1/11	Section 3.0	Updated standard DMA policy template language
7/1/11	Section 4.0	Updated standard DMA policy template language
7/1/11	Section 5.0	Cited Federal Regulations that address each specific section and removed extraneous language that is clearly stated in the cited Federal Regulation and some grammatical errors were corrected
7/1/11	Subsection 5.6.2	Revised Health, Safety and Well-being Criteria
7/1/11	Subsection 5.7	Added reference to Electronic Health Record and added requirement than POC be revised and submitted semi-annually
7/1/11	Subsection 5.9	Corrected Federal Regulation Citations
7/1/11	Section 6.0	Updated standard DMA policy template language, Corrected Federal Regulation Citations, and corrected grammatical errors.
7/1/11	Section 7.0	Updated standard DMA policy template language, cited Federal Regulations that address each specific section or subsection and removed extraneous language that is clearly stated in the cited Federal Regulation. Some grammatical errors were corrected and more appropriate terms were used to replace those words that were in the approved clinical coverage policy.
3/12/2012	Throughout	Technical changes to merge Medicaid and NCHC current coverage into one policy.
10/01/2015	All Sections and Attachments	Updated policy template language and added ICD-10 codes to comply with federally mandated 10/1/2015 implementation where applicable.
02/01/2018	All Sections and Attachments	Updated language in the involuntary disenrollment procedure and specific timeframes were added for participant care planning and assessments. Some grammatical errors were corrected and more appropriate terms were used to replace those words that were in the approved clinical coverage policy
03/15/2019	Table of Contents	Added, “To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after November 1, 2019, please contact your PHP.”

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Date	Section Revised	Change
03/15/2019	All Sections and Attachments	Updated policy template language.
01/10/2020	Table of Contents	Updated policy template language, "To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP."
01/10/2020	Attachment A	Added, "Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines".
00/00/0000	Subsection 5.4.1	Added language on the effective date of voluntary disenrollment and added PACE organizations responsibilities. Removed prior Note regarding effective date of disenrollment.
00/00/0000	Subsection 5.4.2	Added language on the effective date of involuntary disenrollment. Added b., e.,and g. Added participant's caregiver to c.
00/00/0000	Subsection 5.4.3	Removed reasons for involuntary disenrollment. Added language that the SAA must review an involuntary disenrollment before it is effective.
00/00/0000	Subsection 5.4.4	Changed subsection from "Effective Date of Disenrollment" to "Disenrollment Responsibilities". Removed requirement that participant is reinstated in other Medicare and Medicaid programs prior to disenrollment. Added the PACE organization responsibilities.
00/00/0000	Subsection 5.6.1	Changed subsection from "Physical, Functional, and Psychosocial Assessment" to "Initial Comprehensive Assessment". Updated language in section related to 42CFR 460.104 to comply with the Final Rule changes of 2019 and 2021.
00/00/0000	Subsection 5.6.2	Added language to comply with Final Rule changes of 2019 to 42CFR 460.106. Changed submission of plan of care to the SAA from 30 days to 45 days following enrollment.
00/00/0000	Subsection 5.6.3	Added language to comply with Final Rule changes of 2019 to 42CFR 460.104
00/00/0000	Subsection 5.6.4	Added language to comply with Final Rule changes of 2019 to 42CFR 460.104 and Final Rule changes of 2021 to 42CFR 460.121.

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Date	Section Revised	Change
00/00/0000	Subsection 5.6.5	Updated language to reflect language contained on the Health and Safety Assessment. Added times the assessment should be completed. Added the requirement for the PACE program to submit the results of the assessment to the SAA.
00/00/0000	Section 5.7	Added language concerning interventions to comply with Final Rule changes of 2019 to 42CFR 460.106. Removed requirement that the plan of care be submitted to the state for approval semi-annually.
00/00/0000	Section 5.8	Added (a)(b) to 42CFR 460.92
00/00/0000	Section 5.10, 5.10.1, 5.10.3, 5.10.4 & 5.10.5	Changed "program" to "organization"
00/00/0000	Subsection 7.1	Added d. to comply with 2019 Final Rule adding 42CFR 460.63 requiring PACE organizations to adopt and implement effective compliance oversight requirements.
00/00/0000	Section 7.2	Added requirement for PACE programs to provide copies of initial and annual Health and Safety Assessments to the SAA. Added language in section related to 42CFR 460.200 to comply with Final Rule changes of 2019 and 2021 specifically, the submission of information and reports to CMS and the SAA.
00/00/0000	Subsection 7.3.2	Changed previously defined CFR from 460.98(d)(1) to 460.98(c)(1-7). Changed "program" to "organization". Removed prior listed services and added required services per CFR as bulleted items.
00/00/0000	Subsection 7.3.3	Changed "physician" to "provider". Added language in section related to 42CFR 460.102 and 42CFR 460.200 to comply with Final Rule changes of 2019 and 2021.
00/00/0000	Section 7.4	Changed section from "Quality Assessment and Performance Improvement Program" to "Quality Improvement". Added references to 42CFR 460.130, 460.136, and 460.138. Added language in section related to 42CFR 460.130 and 42CFR 460.132 to comply with Final Rule changes of 2019.
00/00/0000	Section 7.5	Removed "shall contain the following" after health record in the first paragraph. Added language in section related to 42CFR 460.210 to comply with Final Rule changes of 2021. Added d., e., and f. to the minimum contents of the medical record.

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Date	Section Revised	Change
00/00/0000	Section 7.6	Changed six (6) years to ten (10) years for health records to be maintained after the last entry date or after the date of disenrollment to comply with Final Rule changes of 2019.
00/00/0000	Section 7.7	Added new section and added language in section related to 42CFR 460.122 and 42CFR 460.124 to comply with Final Rule changes of 2019 and 2021.
00/00/0000	Attachment B	Added 42CFR 460.150(c)(2) to the heading and the requirement under this CFR as letter u. to comply with the Final Rule changes of 2019. Removed "or Medicare Part D plan" under letter i. Added requirements for disenrollment under letter i. when a participant becomes Medicare eligible or elects to obtain other Medicare coverage after enrollment to comply with Final Rule changes of 2019. Added to letter b. the requirements for the membership card and removed d. to comply with the Final Rule changes of 2019.

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Attachment A: Claims-Related Information

Attachment A is not applicable to the PACE program

A. Claim Type

Not applicable.

Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.

B. International Classification of Diseases, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS)

Not applicable.

C. Code(s)

Not applicable.

D. Modifiers

Not applicable.

E. Billing Units

Not applicable.

F. Place of Service

Not Applicable

G. Co-payments

Not applicable.

H. Reimbursement

Claims

The PACE organization does not submit claims to Medicare or Medicaid for any service provided to PACE enrollments, in or out of the service area.

Encounter Forms

The PACE program is not required to submit encounter forms to Medicare or Medicaid.

I. Cost of Emergency Care

The PACE program shall pay for all emergency care.

J. Other Payments

As indicated in 42 CFR 460.182(c), the provider shall accept the monthly capitation payment as payment in full for Medicaid participants and may not bill, charge, collect or receive any other form of payment from the SAA or from the participant or caregiver.

Note: For the purposes of this policy, billing does not apply. However, the criteria in **Section 6.0** must apply to receive payment. Refer to **Subsection 6.2**.

K. Capitated Payment and Amounts

Payment for PACE Participants

The state provides a prospective monthly capitated payment for each PACE participant who is eligible for Medicaid assistance, in accordance with Section 1934(d) of the Act and 42 CFR 460.180. The capitation payment amount is specified in the PACE program agreement and is based on the amount the state would otherwise have paid under the State plan if the beneficiaries were not enrolled in PACE.

Payment for Medicare and Medicaid Dually Eligible Beneficiaries

In accordance with 42 CFR 460.180 and 42 CFR 460.182, a PACE program is eligible to receive monthly capitated payments from Medicaid for a beneficiary who is Medicaid eligible or dually eligible for both Medicare and Medicaid when:

a. the organization has been approved by the SAA as a PACE provider;
b. the organization has been approved by CMS as a PACE provider; and
c. all parties have properly executed the three-way agreement between CMS, the SAA, and the PACE organization.

The PACE program is designed to serve individuals who are Medicare and Medicaid dually eligible and must accept the capitation payments from Medicare and Medicaid as payment in full for all services required by the participant.

Private Pay Participants

Federal regulations (42 CFR 460.186) allow the PACE organization to accept private-pay participants and to collect a premium from individuals who are Medicare-only or Medicaid-only beneficiaries. All federal and state enrollment regulations must apply regardless of payer source.

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Attachment B: PACE Enrollment Agreement

Code of Federal Regulation Citation: [42 CFR 460.150(c)(2), 42 CFR §§ 460.152(a)(1) and (2), 460.154, 460.156, 460.158]

The PACE-eligible prospective enrollee (or legal representative) must agree to several enrollment conditions including, but not limited to: having the PACE organization and its provider network as the sole provider of services; giving signed consent for the PACE organization to obtain medical and financial information to verify eligibility; and, agreeing to any applicable monthly premiums or Medicaid spend down obligations. If the prospective PACE enrollee meets the eligibility requirements and signs the PACE enrollment agreement, the effective date of enrollment in the PACE program is on the first day of the calendar month following the date the PACE organization receives the participant's signed enrollment agreement. The PACE organization must submit a timely and accurate enrollment transaction to complete the enrollment in CMS systems. The enrollment agreement must, at a minimum, contain the following information:

a. Applicant's name, sex, and date of birth;
b. Medicare beneficiary status (Part A, Part B, or both) and number, if applicable;
c. Medicaid beneficiary status and number, if applicable;
d. Information on other health insurance, if applicable;
e. Conditions for enrollment and disenrollment in PACE;
f. Description of participant premiums, if any, and procedures for payment of premiums;
g. Notification that a Medicaid participant and a participant who is eligible for both Medicare and Medicaid are not liable for any premiums, but may be liable for any applicable spenddown liability and any amounts due under the post-eligibility treatment of income process;
h. Notification that a Medicare participant may not enroll or disenroll at a Social Security office;
i. Notification that enrollment in PACE results in disenrollment from any other Medicare or Medicaid prepayment plan or optional benefit. Electing enrollment in any other Medicare or Medicaid prepayment plan or optional benefit, including the hospice benefit ~~or Medicare Part D plan,~~ after enrolling as a PACE participant, is considered a voluntary disenrollment from PACE; If a Medicaid-only or private pay participant becomes eligible for Medicare after enrollment in PACE, the participant will be disenrolled from PACE if he or she elects to obtain Medicare coverage other than from the participant's PACE organization.
j. Information on the consequences of subsequent enrollment in other optional Medicare or Medicaid programs following disenrollment from PACE (i.e., conditions that might apply when enrolling in another managed care plan);
k. Description of PACE services available, including all Medicare and Medicaid covered services, and how services are obtained from the PACE organization;
l. Description of the procedures for obtaining emergency and urgently needed out-of-network services;
m. The participant Bill of Rights;
n. Information on the process for grievances and appeals and Medicare/Medicaid phone numbers for use in appeals;
o. Notification of a participant's obligation to inform the PACE organization of a move or lengthy absence from the organization's service area;
p. An acknowledgment by the applicant or representative that he or she understands the requirement that the PACE organization must be the applicant's sole service provider;

q. A statement that the PACE organization has an agreement with CMS and the State Administering Agency that is subject to renewal on a periodic basis and, if the agreement is not renewed, the program will be terminated;
r. The applicant's authorization for disclosure and exchange of personal information between CMS, its agents, the State Administering Agency, and the PACE organization;
s. The effective date of enrollment;
t. The signature of the applicant or his or her designated representative and the date.
u. The State administering agency criteria used to determine if an individual's health or safety would be jeopardized by living in a community setting must be specified in the program agreement.

After the participant signs the enrollment agreement, the PACE organization must give the participant the following:

a. A copy of the enrollment agreement;
b. A PACE membership card~~:~~ that indicates that he or she is a PACE participant and that includes the phone number of the PACE organization
c. Emergency information to be posted in his or her private residence identifying the individual as a PACE participant and explaining how to access emergency services;
~~d. Stickers for the participant's Medicare and Medicaid cards, as applicable, which indicate that he or she is a PACE participant and which include the phone number of the PACE organization.~~

If there are changes in the enrollment agreement information at any time during the participant's enrollment, the PACE organization must meet the following requirement*s*:

a. Give an updated copy of the information to the participant;
b. Explain the changes to the participant and his or her representative or caregiver in a manner they understand.