

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

Chapter 17 – Application and Waiver Processes, and Program Agreement Requirements

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(Rev. 2, Issued: 06-09-11)

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10 - Overview of CMS and State Administering Agency Roles and Responsibilities

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

The regulations issued by CMS for PACE, issued November 24, 1999, established requirements for PACE under the Medicare and Medicaid programs. The second regulation published on October 1, 2002, incorporated revisions to the original regulation, implementing Section 903 of MIPPA (Pub. L. 106–554) by establishing a process through which PACE organizations may request waiver of certain regulatory requirements. In addition, it provided for greater flexibility in adapting the PACE service delivery model to the needs of the particular organization and removed the requirement that PACE organizations directly employ the interdisciplinary team, the program director, and medical director and allowed for these positions to be contracted. The final rule incorporating response to comments and updates to the regulation was published December 8, 2006.

Section 1905(a)(26) of the Act, as added by Section 4802(a)(1) of the BBA, provided authority for States to elect PACE as an optional Medicaid benefit. States notify CMS that they have elected PACE as an option via a State Plan Amendment that is to be submitted to CMS by the State Medicaid Agency. Each State is required to have a State Administering Agency that is responsible for administering PACE Program Agreements in their State. The State Medicaid Agency may or may not be the State Administering Agency. The State Administering Agency closely cooperates with CMS in establishing procedures for entering into, extending, and terminating PACE Program Agreements. The State Administering Agency also cooperates with CMS in conducting oversight reviews of PACE programs and has the authority to terminate a PACE Program Agreement for cause.

The State Administering Agency is responsible for conducting a readiness review during the application approval process to ensure that the PACE center meets the regulatory requirements for environment and staffing.

It is the responsibility of the PACE organization and the State Administering Agency to validate the information contained in each application. The Director of the State Administering Agency confirms review and approval of the application by submitting a signed certification with the application.

20 - CMS

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

20.1 - Provider Application

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

Information requested in the provider application is based on Sections 1894 and 1934 of the Social Security Act, and the regulations at 42 CFR § 460.2 thru 460.210.

An individual authorized to act for the entity must submit to CMS a complete application that describes how the entity meets all requirements of Part 460. It is the responsibility of the PACE organization and the State Administering Agency to validate the information contained in each application. An entity's application must be accompanied by an assurance from the State Administering Agency of the State in which the program is located indicating that the State considers the entity to be qualified to be a PACE organization and is willing to enter into a PACE program agreement with the entity.

A completed application includes:

- Cover Sheet with the appropriate signatures;
- Table of Contents for the Narrative part;
- Table of Contents for Documents part;
- Narrative part, with each question copied and brief and precise answers, divided into chapters;
- Documents part, arranged by chapters; this part should follow the Narrative. Materials such as marketing brochures and booklets should be inserted in envelopes in the appropriate places in the application. The envelope should be numbered as a single page.

The PACE Provider Application and related resources are located on the CMS webpage at:

http://www.cms.hhs.gov/PACE/06_ProviderApplicationandRelatedResources.asp#TopOfPage.

This Provider Application has been updated to reflect the provisions of the December 2006 final PACE regulation. This file is in a zipped rich text format so States can download a writable version for submission. It also contains appendices (including the Provider Arrangements File, Insurance Coverage File, and Payment Information Form) that must be submitted to CMS as part of the PACE Provider Application.

CMS evaluates an application for approval as a PACE organization on the basis of the information contained in the application, information obtained through onsite visits conducted by CMS or the State Administering Agency, and information obtained by the State Administering Agency.

An entity must state in its application the service area it proposes for its program. CMS, in consultation with the State Administering Agency, may exclude from designation an area that is already covered under another PACE program agreement to avoid unnecessary duplication of services and avoid impairing the financial and service viability of an existing program.

A PACE application can be submitted at any time during the year. As stated in 42 CFR § 460.20, within 90 days after an organization submits a complete application to CMS, CMS can (1) approve the application; (2) deny the application and notify the entity in writing of the basis for denial and the process for requesting reconsideration of the denial; or (3) request additional information needed to make a final determination. Upon receipt of all of the responses to the request for additional information and the completed State Readiness Review, CMS has an additional 90 days to either approve the application or disapprove the application and notify the entity in writing of the basis for the denial and the process for requesting reconsideration of the denial. An application is deemed approved if CMS fails to act on the application within 90 days after the date the application is submitted by the organization or the date CMS receives all requested additional information. For purposes of the 90-day time limit, the date that an application is submitted to CMS is the date on which the application is delivered to the address designated by CMS.

[42 CFR §§ 460.12(a)(1) and (b), 460.18, 460.20, 460.22, 460.72]

20.2 – Part D Application

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

PACE provider applicants must also submit a separate Medicare Prescription Drug Part D application and bid to participate in the PACE program. Part D bids are submitted electronically via the Health Plan Management System (HPMS); applicants must apply for system access and be assigned a CMS user ID in order to submit the Part D bid. Applicants must use the H number assigned to their organization application when submitting a bid. Instructions and templates for completing the Part D bid are downloadable from HPMS.

Final approval of the PACE provider application is contingent upon completion and acceptance of the Part D application and bid approval. The PACE Part D application and instructions are located on the CMS webpage at:

http://www.cms.hhs.gov/PrescriptionDrugCovContra/04_RxContracting_ApplicationGuidance.asp.

[42 CFR §§423, 460]

20.3 - Limit on the Number of PACE Program Agreements

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

There is a limit on the number of PACE program agreements that may be in effect on August 5 of each year, the anniversary of the PACE statute. The number of PACE organizations with which agreements are in effect, are not permitted to exceed:

- 40 as of August 5, 1997, the date of enactment of the PACE statute, or
- As of each succeeding anniversary of that date, the numerical limitation for the preceding year plus 20.

Based on the statutory language, CMS may enter into up to 80 PACE program agreements as of August 5, 1999, and the limit on the number of PACE program agreements increases by 20 each year thereafter.

[42 CFR § 460.24]

20.4 - Expansion Application

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

The most current version of the **PACE Expansion Application** is available at http://www.cms.hhs.gov/PACE/07_Expansions.asp#TopOfPage.

The application is required for PACE organizations wishing to expand their service area or add a new PACE center. In order to ensure quality of care for PACE participants, CMS will only approve an expansion application after an organization has completed the first trial period audit and achieved an acceptable corrective action plan for the initial PACE center and service area.

There are three scenarios under which a PACE provider may expand operations. Each scenario described below contains a list of steps that must be followed for expansion approval.

20.5 - Scenario 1

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

A PACE Organization requests to expand its geographic service area without building additional sites:

- PACE organization must obtain approval for expansion from State Medicaid Agency (SMA) and State Administering Agency;
- PACE organization and State Administering Agency collaborate on the provider application in its entirety. To the extent the expanded service area reflects the same processes as the already approved service area of the provider, the application can note this without resubmitting approved material;
- For an expansion application for a geographic service area expansion only, CMS has 45 days to request additional information or approve the application. Upon the receipt of responses to the request for additional information, CMS has an additional 45 days to either approve or disapprove the application;
- If approved, the Program Agreement's Appendix C is amended to reflect the new service area.

20.6 - Scenario 2

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

A PACE Organization requests to open another physical site in the existing geographic service area:

- PACE organization must obtain approval for expansion from State Medicaid Agency and State Administering Agency;
- PACE organization and State Administering Agency collaborate on the provider application in its entirety. To the extent the new site adopts the same processes as the already approved sites of the provider, the application can note this without resubmitting approved material;
- The State Administering Agency conducts a State Readiness Review of the new site while the clock is stopped;
- For an expansion application for only a new center within an existing geographical area, CMS has 45 days to request additional information or approve the application. Upon completion of the State Readiness Review and receipt of responses to the Request for Additional Information, CMS has an additional 45 days to either approve or disapprove the application;
- If approved, the Program Agreement's Appendix C is amended to reflect the new site.

20.7 - Scenario 3

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

A PACE Organization requests to expand its geographic service area and open another physical site in the expanded area:

- PACE organization must obtain approval for expansion from State Medicaid Agency and State Administering Agency;
- PACE organization and State Administering Agency collaborate on the provider application in its entirety. To the extent the new site adopts the same processes as the already approved sites of the provider, the application can note this without resubmitting approved material;
- The State Administering Agency conducts a readiness review of the new site while the clock is stopped;
- For an application to expand both service area and add a new center, CMS has 90 days to either request additional information or approve the application. Upon completion of the State Readiness Review and receipt of the responses

to the request for additional information, CMS has an additional 90 days to either approve or disapprove the application;

- If approved, the Program Agreement's Appendix C is amended to reflect the new geographic area and new site.

http://www.cms.hhs.gov/PACE/07_Expansions.asp#TopOfPage

20.8 - BIPA 903 Waivers

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

The purpose of the waivers is to provide for reasonable flexibility in adapting the PACE model to the needs of particular organizations (such as those in rural areas). Sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act provide for reasonable flexibility in adapting the PACE service delivery model to the needs of particular organizations and permit the Secretary, in close consultation with State Administering Agencies, to modify or waive provisions of the PACE regulations so long as any such modification or waiver is not inconsistent with and would not impair the essential elements, objections, and requirements of these sections. These sections state that the following provisions may not be modified or waived:

- The focus on frail elderly qualifying individuals who require the level of care provided in a nursing facility;
- The delivery of comprehensive, integrated acute and long-term care services;
- The IDT approach to care management and service delivery;
- Capitated, integrated financing that allows the provider to pool payments received from public and private programs and individuals; and
- The assumption by the provider of full financial risk.

The CMS advises PACE organizations to engage in dialogue with their State Administering Agency regarding considerations for waiver requests prior to preparing formal requests. This will help to ensure mutual understanding and agreement among parties involved, preventing unnecessary work on the part of the PACE organization.

The following CMS link provides instructions for both PACE organizations and State administering agencies in submitting BIPA 903 waivers to CMS:

http://www.cms.hhs.gov/PACE/08_BIPA903WaiverRequests.asp#TopOfPage.

Instructions to PACE organizations for preparing and submitting waiver requests to State Administering Agencies under the authority of Section 903 of the BIPA are as follows:

- Any PACE organization that identifies the need for a BIPA 903 waiver should include the following information in their waiver submission package:
 - Identification that the submitted document is a waiver request;
 - Identification of the regulatory section the PACE organization is requesting to have waived;
 - Rationale behind the waiver request;
 - If applicable, process that will be followed to ensure participant care is not compromised; and
 - Identification as to whether the issue was previously submitted as a BIPA 902 grandfathering request or if it is a new request under Section 903 of BIPA;
- Waiver requests may be submitted to the State under either of the following situations:
 - Waiver request as a document separate from an application but accompanying an application; or
 - Waiver request independent of an application.

Waiver requests submitted in conjunction with provider applications must be marked as separate documents by placing them in an independent envelope labeled "waiver request." Waiver requests submitted independent of an application, as stand-alone documents, must also be clearly labeled "waiver request".

Waiver requests must be submitted to the State Administering Agency. The request will be reviewed by the State and then forwarded to CMS along with any concerns or conditions. CMS evaluates a waiver request from a PACE organization or PACE applicant on the basis of the following information: (1) the adequacy of the description and rationale for the waiver provided by the PACE organization or PACE applicant, including any additional information requested by CMS; and (2) information obtained by CMS and the State Administering Agency in on-site reviews and monitoring of the PACE organization. Within 90 days after receipt of a waiver request, CMS either approves the request or denies the request and notifies the PACE organization or PACE applicant in writing of the basis of the denial. For purposes of the 90-day time limit, the date that a waiver request is received by CMS from the State Administering Agency is the date on which the request is delivered to the address designated by CMS. A waiver request is deemed approved if CMS fails to act on the request within 90 days after the date the waiver request is received by CMS. CMS may withdraw approval of a waiver for good cause.

[42 CFR §§ 460.10, 460.26, 460.28]

30 - State

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

30.1 - PACE State Plan Amendment

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

In order to elect PACE as a State plan option, a State Medicaid Agency must submit a State Plan Amendment. The preprint for a State to elect PACE is found at <http://www.cms.hhs.gov/PACE>. The State Plan Amendment must be approved before CMS can enter into a PACE Program Agreement.

[42 CFR § 460.30(c)]

30.2 - State Readiness Review

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

States are responsible for conducting a State Readiness Review at the applicant's site.

The purpose of this review is to determine the organization's readiness to administer the PACE program and enroll participants. The SRR includes a minimum set of criteria established by CMS in conjunction with the States. States are free to add any additional criteria to the State Readiness Review they deem necessary to help them determine if the applicant (1) meets the requirements stipulated in the PACE regulation; (2) has developed policies and procedures consistent with the PACE regulations; and (3) has established the contracts necessary to provide all inclusive, quality care to its participants. Upon completion of the SRR, the State will submit a report of their findings to CMS. More information on the SRR can be found on the CMS website at:

www.cms.hhs.gov/PACE/04_InformationforStateAgencies.asp#TopOfPage.

During the initial and expansion application processes, the second clock may not begin until all of the elements of the State Readiness Review tool are met to the satisfaction of the State and submitted to CMS.

30.3 - State Contract

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

The PACE Program Agreement is a three-way contract between the PACE organization, the State Administering Agency and CMS, and contains the PACE requirements from the Federal statute and regulations. If the State Administering Agency has requirements beyond those in the three-way PACE Program Agreement, those requirements should be addressed in a separate contract between the State and the PACE organization. The PACE three-way program agreement can be an attachment to the State-PACE organization contract. The State contract with the PACE organization cannot be attached

or included as part of the three-way agreement. Each PACE organization must agree to meet all applicable requirements under Federal, State, and local laws and regulations.

States may implement additional or more stringent requirements if they are consistent with Sections 1894 and 1934 of the Act and with Federal laws and regulations. However, if there is a conflict between the State and Federal requirements, the Federal requirements would take precedence.

[42 CFR §§ 460.30(a), 460.32(a)(2); 71 FR 71258 (Dec. 8, 2006)]

40 - PACE Program Agreement

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

The PACE Program Agreement is the contract executed between CMS, State Administering Agency and the PACE organization upon approval of a permanent PACE provider application.

This three-party contract governs provider operations and is signed by the aforementioned parties. A PACE program agreement must include the following:

- A designation of the service area of the organization's program. The area may be identified by county, zip code, street boundaries, census tract, block, or tribal jurisdictional area, as applicable. CMS and the State Administering Agency must approve any change in the designated service area;
- The organization's commitment to meet all applicable requirements under Federal, State, and local laws and regulations, including provisions of the Civil Rights Act, the Age Discrimination Act, and the Americans With Disabilities Act;
- The effective date and term of the agreement;
- A description of the organizational structure of the PACE organization and information on administrative contacts including the name and phone number of the program director, the name of all governing body members, and the name and phone number of a contact person for the governing body;
- A participant bill of rights approved by CMS and an assurance that the rights and protections will be provided;
- A description of the process for handling participant grievances and appeals;
- A statement of the organization's policies on eligibility, enrollment, voluntary disenrollment, and involuntary disenrollment;
- A description of services available to participants;

- A description of the organization's quality assessment and performance improvement program;
- A statement of the levels of performance required by CMS on standard quality measures;
- A statement of the data and information required by CMS and the State Administering Agency to be collected on participant care;
- The Medicaid capitation rate and the methodology used to calculate the Medicare capitation rate; and
- A description of procedures that the organization will follow if the PACE program agreement is terminated.

Additionally, an agreement may provide additional requirements for individuals to qualify as PACE program eligible individuals in accordance with 42 CFR § 460.150(b)(4) and may contain any additional terms and conditions agreed to by the parties if the terms and conditions are consistent with sections 1894 and 1934 of the Act and the Part 460 regulations.

Additional information about the program agreement can be found on the CMS website at:

http://www.cms.hhs.gov/PACE/06_ProviderApplicationandRelatedResources.asp#TopOfPage.

The program agreement is effective for a contract year and may be extended for subsequent contract years in the absence of a notice by a party (CMS, State Administering Agency, or the PACE organization) to terminate the agreement. The first contract year can extend up to 23 months, that is, to December 31st of the year following the effective date of the contract.

CMS or the State Administering Agency may terminate the program agreement at any time for cause, including, but not limited to, uncorrected deficiencies in the quality of care furnished to participants, the PACE organization's failure to comply substantially with the conditions for a PACE program, or non-compliance with the terms of the agreement. The PACE organization may terminate the program agreement after timely notice to CMS, the State Administering Agency and the participants. Notifications shall be made as follows: 90 days before termination to CMS and the State Administering Agency and 60 days before termination to the participants.

[42 CFR §§ 460.6, 460.30(b), 460.32, 460.34, 460.50]

50 - Effect of Change of Ownership

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

CMS requires disclosure of any organizational changes that affect the philosophy, mission, and operations of the PACE organization and impact care delivery to participants. CMS believes that any change in ownership, relationships to another corporate board and to any parent, affiliate, or subsidiary corporate entities, the PACE governing body, its officials, program director, and medical director could result in a substantial impact on the participants and their care. This does not include changes in personnel or a change in the line of reporting of direct participant care staff.

CMS requires any PACE organization that is planning a change in organizational structure to notify CMS and the State Administering Agency, in writing, at least 14 days before the change takes place.

[42 CFR § 460.60(d)(3); 71 FR 71264 (Dec. 8, 2006)]

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R2PACE	06/09/2011	Initial Publication of Manual	06/03/2011	NA
R1_SO	06/03/2011	Initial Publication of Manual - Rescinded and replaced by Transmittal 2	06/03/2011	NA

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