

# **PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY**

**For all new applicants seeking to become a PACE Organization**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Medicare & Medicaid Services (CMS)  
Center for Medicare (CM)  
Medicare Drug and Health Plan Contract Administration Group  
(MCAG)**

**2016**

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**Contents**

- 1 GENERAL INFORMATION..... 4**
  - 1.1 Overview ..... 4
  - 1.2 Technical Support ..... 6
  - 1.3 The Health Plan Management System (HPMS) ..... 8
  - 1.4 Submitting Notice of Intent to Apply (NOIA)..... 9
  - 1.4.A Protecting Confidential Information ..... 9
  - 1.5 Application Determination and Appeal Rights..... 10
  
- 2 INSTRUCTIONS ..... 11**
  - 2.1 Overview ..... 11
  - 2.2 Types of Applications ..... 11
  - 2.3 Chart of Required Attestations..... 11
  - 2.4 Document (Upload) Submission Instructions ..... 13
  - 2.5 Part D Prescription Drug Benefit Instructions ..... 13
  
- 3 ATTESTATIONS ..... 14**
  - 3.1 Service Area..... 14
  - 3.2 Legal Entity and Organizational Structure ..... 15
  - 3.3 Governing Body ..... 16
  - 3.4 Fiscal Soundness ..... 17
  - 3.5 Marketing..... 19
  - 3.6 Explanation of Rights ..... 21
  - 3.7 Grievances..... 22
  - 3.8 Appeals ..... 23
  - 3.9 Enrollment..... 25
  - 3.10 Disenrollment..... 28
  - 3.11 Personnel Compliance ..... 31
  - 3.12 Program Integrity ..... 33
  - 3.13 Contracted Services ..... 34
  - 3.14 Required Services ..... 35
  - 3.15 Service Delivery..... 36
  - 3.16 Infection Control..... 37
  - 3.17 Interdisciplinary Team ..... 38
  - 3.18 Participant Assessment ..... 39
  - 3.19 Plan of Care..... 41
  - 3.20 Restraints..... 42
  - 3.21 Physical Environment ..... 43
  - 3.22 Emergency and Disaster Preparedness ..... 44
  - 3.23 Transportation Services ..... 45
  - 3.24 Dietary Services ..... 46
  - 3.25 Terminations ..... 47
  - 3.26 Maintenance of Records & Reporting Data..... 48
  - 3.27 Medical Records ..... 49
  - 3.28 Quality Assessment Performance Improvement Program (QAPI) ..... 50

3.29	State Attestations .....	52
3.30	Waivers .....	53
3.31	Application Attestations.....	53
3.32	State Readiness Review .....	53
<b>4</b>	<b>Document Upload Templates.....</b>	<b>54</b>
4.1	Governing Body.....	54
4.2	Subordinated Debt .....	55
4.4	State Medicaid Capitation Payment.....	58
4.5	State Continued Eligibility SOP .....	60
4.6	State Enrollment and Disenrollment SOP.....	60
4.7	Applicant Attestations.....	61
4.8	State Readiness Review .....	63

# **1 GENERAL INFORMATION**

## **1.1 Overview**

### Demonstration Project

Section 603(c) of the Social Security Amendments of 1983 (Pub. L. 98-21), as extended by section 9220 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) (Pub. L. 99-272) authorized the original demonstration PACE program for On Lok Senior Health Services (On Lok) in San Francisco. Section 9412(b) of Pub. L. 99-509, the Omnibus Budget Reconciliation Act of 1986 (OBRA, 1986), authorized CMS to conduct a PACE demonstration program to determine whether the model of care developed by On Lok could be replicated across the country. The number of sites was originally limited to 10, but the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101-508) authorized an increase to 15 PACE demonstration programs. The PACE demonstration program was operated under a Protocol established and published by On Lok, Inc. on April 4, 1995.

The PACE model of care includes, as core services, the provision of adult day health care and interdisciplinary team (IDT) care management, through which access to and allocation of all health services is managed. Physician, therapeutic, ancillary, and social support services are furnished in the participant's residence or onsite at a PACE center. Hospital, nursing home, home health, and other specialized services are generally furnished under contract. Financing of the PACE demonstration model was accomplished through prospective capitation of both Medicare and Medicaid. PACE demonstration programs had been permitted by section 4118(g) of Pub. L. 100-203 (OBRA 1987) to assume full financial risk progressively over the initial three years. As such authority was removed by section 4803(b)(1)(B) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33), PACE demonstration programs approved after August 5, 1997 had to assume full financial risk at start-up.

### Balanced Budget Act of 1997 (BBA)(Pub. L. 105-33)

Section 4801 of the BBA authorized coverage of PACE under the Medicare program by amending title XVIII of the Social Security Act ("the Act") and adding section 1894, which addresses Medicare payments and coverage of benefits under PACE. Section 4802 of the BBA authorized the establishment of PACE as a state option under Medicaid by amending title XIX of the Act and adding section 1934, which directly parallels the provisions of section 1894. Section 4803 of the BBA addresses implementation of PACE under both Medicare and Medicaid, the effective date, timely issuance of regulations, priority and special consideration in processing applications, and transition from PACE demonstration program status.

As directed by section 4803 of BBA, we published an interim final rule on November 24, 1999 permitting entities to establish and operate PACE programs under section 1894 and 1934 of the Act(64 FR 66234).The 1999 interim final rule was a comprehensive rule that addressed eligibility, administrative requirements, application procedures, services, payment, participant rights, and quality assurance.

The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA)(Pub. L. 106-554)

BIPA modified the PACE program in the following three ways:

- Section 901 extended the transition period for the PACE demonstration programs to allow an additional year for these organizations to transition to the permanent PACE program.
- Section 902 gave the Secretary the authority to grandfather in the modifications these programs had implemented as of July 1, 2000. This provision allowed the PACE demonstration programs to continue program modifications they had implemented and avoid disruptions in participant care where these modifications were determined to be consistent with the PACE model. These sections were implemented administratively.
- Section 903 specifically addressed flexibility in exercising the waiver authority provided under sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act. It authorized CMS to modify or waive PACE regulatory provisions in a manner that responds promptly to the needs of PACE organizations (POs) relating to the areas of employment and the use of community-based primary care physicians. Section 903 of BIPA also established a 90-day review period for waiver requests. Because the flexibility language is part of the statutory section dealing with regulations (sections 1894(f) and 1934(f) of the Act), we believed it was intended that waiver requirements be incorporated into the PACE regulations. In 2002, we issued an interim final rule with comment period to implement section 903 of BIPA by establishing a process through which a PO may request waiver of certain Medicare and Medicaid requirements. This rule also revised some of the provisions set forth in the 1999 interim final rule related to the requirements for submission and evaluation of waiver requests.

Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173)

On December 8, 2003, the Congress enacted the MMA of 2003 (Pub. L. 108-173). Several sections of the MMA impact POs. Most notably, section 101 of the MMA affected the way in which POs are paid for providing certain outpatient prescription drugs to any Part D eligible participant. As specified in sections 1894(b)(1) and 1934(b)(1) of the Act, POs shall provide all medically necessary services including prescription drugs, without any limitation or condition as to amount, duration, or scope and without application of deductibles, co-payments, coinsurance, or other cost sharing that would otherwise apply under Medicare or Medicaid. The MMA altered the payment structure for Part D drugs for POs by shifting the payer source for PACE enrollees who are full-benefit dual-eligible individuals from Medicaid to Medicare, and, in part, from the beneficiary to Medicare in the case of non-full-benefit dual-eligible individuals who elect to enroll in Part D. The MMA did not impact the manner in which POs are paid for the provision of outpatient prescription drugs to non-part D eligible PACE participants.

Section 1860D-21(f) of the Act, added by section 101 of the MMA, provides that POs may elect to provide qualified prescription drug coverage to enrollees who are Part D eligible individuals. The MMA allows CMS the flexibility to deem POs as MA-PD local plans or to treat POs that

elect to provide qualified drug coverage in a manner similar to MA-PD local plans. Due to inconsistencies in the PACE and MMA statutes, we chose to treat POs in a similar manner as MA-PD plans, thereby avoiding conflicting requirements. The requirements that apply to POs that elect to provide qualified prescription drug coverage to Part D eligible enrollees are set forth in subpart T of the preamble to the Part D final rule (70 FR 4426 through 4434).

In addition, section 236 of the MMA amended the Act to extend to POs the existing statutory Medicare and Medicaid balance billing protections that had previously applied to POs under PACE demonstration program authority. Specifically, provisions of the Act that limit balance billing against MAOs by non-contract physicians, providers of service, and other entities with respect to services covered under title XVIII now include PACE providers. Similarly, Medicaid billing limitations specified in the Act now apply to providers participating under the State plan under title XIX that do not have a contract or other agreement with a PACE provider. Both MMA provisions apply to services furnished on or after January 1, 2004.

Section 301 of the MMA amends the Medicare Secondary Payer (MSP) provisions in section 1862(b) of the Act. These amendments clarify the obligations of primary plans and primary payers, the nature of the insurance arrangements subject to the MSP rules, the circumstances under which Medicare may make conditional payments, and the obligations of primary payers to reimburse Medicare. In order to implement section 301 of the MMA, we issued an interim final rule with comment period (71 FR 9466), published on February 24, 2006, revising our MSP regulations at part 411. Our PACE regulations at §460.180(d) specify that Medicare does not pay for PACE services to the extent that Medicare is not the primary payer under part 411. The interim final rule establishes our current policies regarding the obligations of other payers.

## 2006 Final Rule

In 2006, we issued a final rule (71 FR 71244, Dec 8, 2006) that finalized both the PACE interim final rule with comment period published in the Federal Register November 24, 1999 (64 FR 66234) and the PACE interim final rule with comment period published in the Federal Register on October 1, 2002 (67 FR 61496).

For a complete history of the PACE program, please see 71 FR 71244 through 71248 (Dec. 8, 2006).

People with Medicare not only have more quality health care choices than in the past but also have more information about those choices. The Centers for Medicare & Medicaid Services (CMS) welcomes organizations that can add value to these programs, make them more accessible to Medicare beneficiaries, and meet all the contracting requirements.

## 1.2 **Technical Support**

CMS conducts special training sessions for all new PACE applicants. All applicants are strongly encouraged to participate in these sessions, which are announced via the HPMS and/or the CMS main website.

CMS Central Office (CO) staff and Regional Office (RO) staff are available to provide technical support to all applicants during the PACE application process. While preparing the application, applicants may send an email by going to <https://dmao.lmi.org/> and clicking on the PACE tab. Please note: this is a webpage, not an email address.

Below is a list of CMS RO contacts.

This information is also available at:

<https://www.cms.gov/RegionalOffices/>

**RO I CMS – BOSTON REGIONAL OFFICE**

John F. Kennedy Federal Building, Room 2325, Boston, MA 02203 Telephone: 617-565-1267

States: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont

**RO II CMS – NEW YORK REGIONAL OFFICE**

26 Federal Plaza, Room 3811, New York, NY 10278

Telephone: 212-616-2353

States: New Jersey, New York, Puerto Rico and Virgin Islands

**RO III CMS – PHILADELPHIA REGIONAL OFFICE**

Public Ledger Building, Suite 216, 150 S. Independence Mall West, Philadelphia, PA 19106-3499

Telephone: 215-861-4224

States: Delaware, District Of Columbia, Maryland, Pennsylvania, Virginia and West Virginia

**RO IV CMS – ATLANTA REGIONAL OFFICE**

Atlanta Federal Center, 61 Forsyth Street, SW, Suite 4T20, Atlanta, GA 30303-8909

Telephone: 404-562-7362

States: Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina and Tennessee

**RO V CMS – CHICAGO REGIONAL OFFICE**

233 North Michigan Avenue, Suite 600, Chicago, IL 60601-5519

Telephone: 312-353-3620

States: Illinois, Indiana, Michigan, Minnesota, Ohio and Wisconsin

**RO VI CMS – DALLAS REGIONAL OFFICE**

1301 Young Street, Room 714, Dallas, TX 75202

Telephone: 214-767-4471

States: Arkansas, Louisiana, Oklahoma, New Mexico and Texas

**RO VII CMS – KANSAS CITY REGIONAL OFFICE**

Richard Bolling Federal Office Building, 601 East 12th Street, Room 235, Kansas City, MO, 64106

Telephone: 816-426-5783  
States: Iowa, Kansas, Missouri and Nebraska

RO VIII CMS – DENVER REGIONAL OFFICE  
1600 Broadway, Suite 700, Denver, CO 80202  
Telephone: 303-844-2111  
States: Colorado, Montana, North Dakota, South Dakota, Utah and Wyoming

RO IX CMS – SAN FRANCISCO REGIONAL OFFICE  
Division of Medicare Health Plans Operations  
90 7<sup>th</sup> Street, Suite 5-300 (5w), San Francisco, CA 94103-6707 Telephone:  
415-744-3602  
States: Arizona, California, Guam, Hawaii, Nevada, American Samoa and The  
Commonwealth of Northern Mariana Islands

RO X CMS – SEATTLE REGIONAL OFFICE  
Blanchard Plaza Building  
2201 Sixth Avenue, MS/RX-40, Seattle, WA 98121 Telephone:  
(206) 615-2306  
States: Alaska, Idaho, Oregon and Washington

### **1.3 The Health Plan Management System (HPMS)**

- A. HPMS is the primary information collection vehicle through which PACE applicants will communicate with CMS during the application process, bid submission process, ongoing operations of the PACE program, reporting and oversight activities.
- B. Applicants are required to enter contact and other information collected in HPMS in order to facilitate the application review process. Applicants must promptly enter organizational data into HPMS and keep the information up to date. These requirements ensure that CMS has current information and is able to provide guidance to the appropriate contacts within the organization. In the event that an applicant is awarded a contract, this information will also be used for frequent communications during contract implementation. Therefore, it is important that this information be accurate at all times. Please note that it is CMS' expectation that the PACE Application Contact is a direct employee of the applicant.
- C. HPMS is also the vehicle used to disseminate CMS guidance to PACE Organizations. This information is then incorporated into the appropriate manuals. It is imperative for PACE organizations to independently check HPMS memos and follow the guidance as indicated in the memos.
- D. Applicants and other interested parties, whom do not have access to HPMS, can stay abreast of current HPMS memos and guidance by subscribing to the Medicare Advantage listserv. Subscribers to the CMS PLAN or INDUSTRY listservs receive memos and guidance regarding Medicare Advantage and Part D prescription drug programs.

If you do not have access to HPMS but would like to receive CMS guidance and memos, simply request to be added to one of the following listservs:

- **PLAN listserv:** Choose this listserv to get HPMS guidance and memos if you are a user that works for an MA or Part D organization but your role in the company does not require HPMS access.
- **INDUSTRY listserv:** Choose this listserv if you are an industry user that is not associated with any existing MA or Part D organization, but work with MA and Part D in some capacity (e.g., consultants, PBMs, doctors, pharmacists, etc).

Please email your request directly to Sara Silver at [Sara.Walters@cms.hhs.gov](mailto:Sara.Walters@cms.hhs.gov). Please indicate in the email which listserv you wish you join. If you wish to join the PLAN listserv please provide the contract number(s) you are associated with.

#### **1.4 Submitting Notice of Intent to Apply (NOIA)**

Organizations interested in becoming a new PACE organization must complete a nonbinding NOIA. CMS will not accept applications from organizations that fail to submit a timely NOIA. Upon submitting the completed form to CMS, the organization will be assigned a pending contract number (H number) to use throughout the application and subsequent operational processes.

Once a contract number is assigned, the applicant should request a CMS User ID. An application for Access to CMS Computer Systems (for HPMS access) is required and can be found at: <https://applications.cms.hhs.gov>. Upon approval of the CMS User ID request, the applicant will receive a CMS User ID(s) and password(s) for HPMS access.

##### **1.4.A Protecting Confidential Information**

Applicants may seek to protect their information from disclosure under the Freedom of Information Act (FOIA) by claiming that FOIA Exemption 4 applies. The applicant is required to label the information in question “confidential” or “proprietary” and explain the applicability of the FOIA exemption it is claiming. When there is a request for information that is designated by the applicant as confidential or that could reasonably be considered exempt under FOIA Exemption 4, CMS is required by its FOIA regulation at 45 CFR 5.65(d) and by Executive Order 12600 to give the submitter notice before the information is disclosed. To decide whether the applicants information is protected by Exemption 4, CMS must determine whether the applicant has shown that: (1) disclosure of the information might impair the government's ability to obtain necessary information in the future; (2) disclosure of the information would cause substantial harm to the competitive position of the submitter; (3) disclosure would impair other government interests, such as program effectiveness and compliance; or (4) disclosure would impair other private interests, such as an interest in controlling availability of intrinsically valuable records, which are sold in the market place. Consistent with our approach under other Medicare programs, CMS would not release information that would be considered proprietary in nature if the applicant has shown it meets the requirements for FOIA Exemption 4.

## **1.5 Application Determination and Appeal Rights**

Pursuant to 42 C.F.R. § 460.20, if CMS denies an application CMS must notify the entity in writing of the basis for the denial and the process for requesting reconsideration of the denial.

If CMS determines that the applicant is not qualified and denies the application, the applicant has the right to appeal this determination through a hearing before a CMS Hearing Officer. Until such time that CMS promulgates regulations for PACE Organizations to appeal application determinations, CMS will be guided by regulations 42 CFR Part 422, Subpart N (Part C) and 42 CFR Part 423, Subpart N (Part D). The request for a hearing must be in writing, signed by an authorized official of the applicant organization, and received by CMS within 15 calendar days from the date CMS notifies the applicant of its determination. If the 15th day falls on a weekend or federal holiday, the applicant has until the next regular business day to submit its request.

CMS recommends that you send the appeal request by fax and/or a traceable carrier (e.g. an overnight mail service which provides you with written delivery confirmation) to ensure timely receipt. Your request for a hearing must include the name, fax number and email address of the contact within your organization with whom you wish us to communicate regarding the hearing request.

Please note that under 42 CFR §422.660, §423.650(b), if an applicant appeals, the applicant has the burden of proving at hearing that the application met the Medicare program requirements within the required timeframe. The applicant will be able to submit evidence to support the appeal to the Hearing Officer. Upon CMS's receipt of the request for an appeal, the Hearing Officer will send the applicant information outlining the submission process for the written explanations (such as position papers) as well as any additional evidence the applicant wishes CMS to consider in regard to the reconsideration request. We recommend that applicants submit these materials as quickly as possible after the receipt of the submission instructions.

NOTE: An applicant submitting material that he or she believes is protected from disclosure under 5 U.S.C. 552, the Freedom of Information Act (FOIA) or, because of exceptions provided in 45 CFR Part 5 (the DHHS's regulations providing exceptions to disclosure), should label the material "privileged" and include an explanation of the applicability of an exception described in 45 CFR Part 5. The foregoing is not a pledge of confidentiality, and the applicant's labeling of material as confidential or privileged does not necessarily exempt such material from undergoing FOIA review by CMS.

## **2 INSTRUCTIONS**

### **2.1 Overview**

Applicants must complete the 2016 PACE application using HPMS as instructed. CMS will only accept submissions using this current 2016 version of the MA application. All documentation must contain the appropriate CMS-issued contract number.

In preparing a response to the prompts throughout this application, the applicant must mark “Yes” or “No” in sections organized with that format. By responding “Yes,” the applicant is certifying that its organization complies with the relevant requirements as of the date the application is submitted to CMS, unless a different date is stated by CMS.

Failure to meet the requirements represented in this application and to operate a PACE plan consistent with the applicable statutes, regulations, and the PACE program agreement, and other CMS guidance could result in the suspension of plan marketing and enrollment. If these issues are not corrected in a timely manner, the applicant will be disqualified from participation in the PACE program, as applicable.

Throughout this application, applicants are asked to provide various documents and/or tables in HPMS. There is a summary of all documents required to be submitted at the end of each attestation section.

CMS strongly encourages PACE applicants to refer to the regulations at 42 CFR 460. Nothing in this application is intended to supersede the regulations at 42 CFR 460. Failure to reference a regulatory requirement in this application does not affect the applicability of such requirement, and applicants are required to comply with all applicable requirements of the regulations. Applicants must read HPMS memos and visit the CMS web site periodically to stay informed about new or revised guidance documents.

### **2.2 Types of Applications**

#### **Initial Applications are for:**

- Applicants who are seeking to become a PACE organization for the first time.

### **2.3 Chart of Required Attestations**

This chart (Chart 1) describes the required attestations for an initial PACE applications. The purpose of this chart is to provide the applicant with a summary of the attestation topics.

Chart 1 - Required Attestations

Attestation Topic	Section #	Initial
Service Area	3.1	X
Legal Entity and Organizational Structure	3.2	X
Governing Body	3.3	X
Fiscal Soundness	3.4	X
Marketing	3.5	X
Explanation of Rights	3.6	X
Grievance	3.7	X
Appeals	3.8	X
Enrollment	3.9	X
Disenrollment	3.10	X
Personnel Compliance	3.11	X
Program Integrity	3.12	X
Contracted Services	3.13	X
Required Services	3.14	X
Service Delivery	3.15	X
Infection Control	3.16	X
Interdisciplinary Team	3.17	X
Participant Assessment	3.18	X
Plan of Care	3.19	X
Restraints	3.20	X
Physical Environment	3.21	X
Emergency and Disaster Preparedness	3.22	X
Transportation Services	3.23	X
Dietary Services	3.24	X
Termination	3.25	X
Maintenance of Records & Reporting Data	3.26	X
Medical Records	3.27	X
Quality Assessment Performance Improvement Program (QAPI)	3.28	X
State Attestations	3.29	X
Waivers	3.30	X
Application Attestations	3.31	X
State Readiness Review	3.32	X

## **2.4 Document (Upload) Submission Instructions**

PACE applicants must include their assigned H number in the file name of all submitted documents. Applicants are encouraged to be descriptive in naming all files.

## **2.5 Part D Prescription Drug Benefit Instructions**

The Medicare Part D Application for new PACE organizations is to be completed by those newly forming PACE organizations that intend to provide the Part D benefit to eligible participants beginning in 2016. Applicants must use the 2016 solicitation. CMS will not accept or review in any way those submissions using prior versions of the application.

The Medicare Part D application for new PACE organizations for contract can be found at: [http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting\\_ApplicationGuidance.html](http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ApplicationGuidance.html).

Note: Failure to submit the required Part D Application for PACE applicants will render the Part D Application incomplete and could result in the denial of this application.

### 3 ATTESTATIONS

#### 3.1 Service Area

The purpose of this section is to ensure that all PACE applicants define the proposed geographic area that will be served consistent with the requirements of 42 CFR §460.22, §460.70, and §460.98.

A. In HPMS, complete the table below:

<b>RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: SERVICE AREA</b>	<b>YES</b>	<b>NO</b>
1. Applicant ensures that contracted services are accessible to participants and located near or within the geographic service area as specified in 42 CFR §460.70(b)(2).		
2. Applicant agrees to operate at least one PACE center within or contiguous to the geographic service area with capacity to allow routine attendance by participants as specified in 42 CFR §460.98(d)(1).		
3. Applicant's defined geographic service area does not duplicate a service area covered by another PACE program agreement as permitted in 42 CFR §460.22(a)(b).		

B. In the Documents Section, upload a detailed map, with a scale of the complete geographic service area that includes county, zip code, street boundaries, census tract or block or tribal jurisdiction and main traffic arteries, physical barriers such as mountains and rivers and location of the PACE center, hospital providers, ambulatory and institutional services sites. Depict on the map the mean travel time from the farthest points on the geographic boundaries to the nearest ambulatory and institutional service sites. If the geographic service area includes an area covered by another PACE organization, identify the duplicate area.

Note: The map must be developed in accordance with 42 CFR §460.22, §460.70, and §460.98.

**3.2 Legal Entity and Organizational Structure**

The purpose of this section is to ensure that all PACE applicants are organized under State law and have a current chart outlining the organizational structure consistent with the requirements of 42 CFR §460.60.

A. In HPMS, complete the table below:

<b>RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: LEGAL ENTITY AND ORGANIZATIONAL STRUCTURE</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>
1. Applicant ensures that the corporate entity that signs the Program Agreement has the legal authority to do so.			
2. Applicant agrees that the Program Director is responsible for oversight and administration of the entity (42 CFR §460.60(b)).			
3. Applicant agrees that the Medical Director is responsible for delivery of participant care, clinical outcomes and implementation and oversight of the quality assessment and performance improvement (QAPI) program (42 CFR §460.60(c)).			
4. Applicant agrees to maintain an up-to-date organizational chart indicating the persons and titles of all officials in the PACE organization (42 CFR §460.60(d)).			
5. Applicant agrees to indicate relationships to the corporate board, parent, affiliates, and subsidiary corporate entities in an organizational chart.  Note: If the applicant is not part of a corporate entity, then the applicant should respond "N/A"			
6. Applicant agrees to notify CMS and SAA in writing at least 14 days before a change in the organizational structure takes effect (42 CFR §460.60 (d)(3)).			
7. Applicant ensures that they are organized to operate within the state consistent with all applicable state laws.			
8. If planning to do business as (d.b.a.) under a name that is different from the names of the organization, applicant attests that it has state approval for the d.b.a.			

B. In the Documents Section, upload a description of the organizational structure of the PACE organization, including the relationship to, at a minimum, the governing body,

program director, medical director, and to any parent, affiliate or subsidiary entity.

**3.3 Governing Body**

The purpose of this section is to ensure that all PACE applicants have appropriate resources and structures available to effectively and efficiently manage administrative issues associated with PACE organization operations and participant concerns consistent with the requirements of 42 CFR §460.62.

A. In HPMS, complete the table below:

<b>RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: GOVERNING BODY</b>	<b>YES</b>	<b>NO</b>
1. Applicant ensures operation under an identifiable governing body such as a board of directors or a designated person functioning as such who provides oversight and authority for the following functions: <ul style="list-style-type: none"> <li>• Governance and operation;</li> <li>• Development of policies consistent with its mission;</li> <li>• Management and provision of all services, including the management of subcontractors;</li> <li>• Personnel policies (that address adequate notice of termination by employees or contractors with direct participant care responsibilities);</li> <li>• Fiscal operations;</li> <li>• Development of policies on participant health and safety; and</li> <li>• QAPI program. (see 42 CFR §460.62(a)(1-7))</li> </ul>		
2. Applicant ensures a Participant Advisory Committee is established of which the majority consists of participants and participant representatives who advise the governing body on participant concerns and provide them with meeting minutes that include participant issues (42 CFR §460.62(b)(2)).		
3. Applicant agrees to appoint a participant representative to act as a liaison between the governing body and Participant Advisory Committee, to present participant issues to the governing body and to ensure community representation (42 CFR §460.62(b)(1)).		

B. In the Documents Section, upload a current list of the members of the Board of Directors and their titles. Indicate which, if any, members are consumer representative. Include the name and phone number of a contact for the governing body and the name and phone number of the PACE Program director responsible for oversight and administration as described in 42 CFR §460.6(b).

### 3.4 Fiscal Soundness

The purpose of this section is to ensure that all PACE applicants meet the financial requirements consistent with 42 CFR §460.80, §460.204, and §460.208.

A. In HPMS, complete the table below:

<b>RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: FISCAL SOUNDNESS</b>	<b>YES</b>	<b>NO</b>
1. Applicant agrees to maintain a fiscally sound operation as specified in 42 CFR §460.80(a)(1-3): <ul style="list-style-type: none"> <li>• Total assets greater than total unsubordinated liabilities;</li> <li>• Sufficient cash flow and adequate liquidity to meet obligations as they become due; and</li> <li>• A net operating surplus or a financial plan for maintaining solvency that is satisfactory to CMS and the State administering agency (SAA).</li> </ul>		
2. Applicant agrees to upload a documented plan in the event of insolvency as specified in 42 CFR §460.80(b).		
3. Applicant agrees to upload CMS and the SAA with accurate financial reports as specified in 42 CFR §460.204.		
4. Applicant agrees to submit quarterly and annual certified financial statements in a format acceptable to CMS and the SAA as specified in 42 CFR §460.208.		
5. Applicant agrees to upload CMS a copy of the executed subordinated debt agreement for each financial reporting period (if applicable).		

B. In the Documents Section, upload a description of any reserve requirements and other financial requirements set by the State and supporting documentation to demonstrate how the applicant meets these requirements.

C. In the Documents Section, upload the independently audited financial statement for the three most recent fiscal year periods or, if operational for a shorter period of time, for each operational fiscal year.

Note: If a PACE program is a line of business of the applicant, it should provide audited statements relating to the legal entity. Audits provided in the Documents section of the application, are to include:

- Opinion of a certified public accountant;
- Statement of revenues and expense;
- Balance sheet;
- Statement of cash flows;
- Explanatory notes; and

- Statements of changes in net worth.

- D. In the Documents Section, upload the most recent year-to-date unaudited financial statement of the entity and independently audited financial statements of guarantors and lenders (e.g. organizations providing loans, letters of credit or other similar financing arrangements, excluding banks).
- E. In the Documents Section, upload financial projections.

Note: Provide financial projections beginning with program commencement through one year beyond break-even. -(Financial projections should be prepared using the accrual method of accounting in conformity with generally accepted accounting principles (GAAP). Prepare projections using the pro-forma financial statement methodology. -For a line of business, assumptions need only be submitted to support the projections of the line.) Projections must include:

- Opening and annual balance sheet
  - Quarterly statements of revenues and expenses for legal entity
  - Give projections in gross dollars and include year-end totals. (In cases where the plan is a line of business, the applicant should also complete a statement of revenue and expenses for the line of business).
- Statement and justification of assumptions;
  - State major assumptions in sufficient detail to allow an independent financial analyst to reconstruct projected figures using only the stated assumptions;
  - Include operating and capital budget breakdowns;
  - Stated assumptions should address all periods for which projections are made and include inflation assumptions
  - Justify assumptions to the extent that an independent financial analyst would be convinced that they are reasonable; and
  - Base justification on such factors as the applicant's experience and the experience of other PACE organizations.

- F. In the Documents Section, upload evidence of applicant's financing arrangements for any projected deficit.
- G. In the Documents Section, upload your Insolvency Plan.
- H. In the Documents Section, upload documents that demonstrate you can, in the event it becomes insolvent, cover expenses of at least the sum of one month's total capitation revenue to cover expenses the month prior to insolvency and one month's average payment to all contractors, based on the prior quarter's average payment, to cover expenses the month after the date insolvency is declared or operations cease. (Arrangements to cover expenses may include, but are not limited to, insolvency insurance or reinsurance, hold harmless arrangements, letters of credit, guarantees, net worth, restricted state reserves or State law provisions.)

I. In the Document Section, upload your attestation on your subordinated debt arrangements.

Note: The agreement must include the amount (whether it changes or not) and the account name under which the subordinate debt falls. (Subordinated debt is unsecured debt, which refers to any type of debt or general obligation that is not collateralized by a lien on specific assets of the borrower in the case of bankruptcy, liquidation or failure to meet the terms for repayment, whose repayment to its parent company or another lending entity ranks after all other debts have been paid when the subsidiary files for bankruptcy. It can also be defined as a loan that ranks below all other loans with regard to claims on assets or earnings).

J. In the Documents Section upload a copy of the applicant's most recent Insurance Protection table to summarize insurance or other arrangements for major types of loss and liability in accordance with 42 CFR §460.80.

### 3.5 **Marketing**

The purpose of this section is to ensure that all PACE applicants develop a plan for marketing and marketing materials consistent with the requirements of 42 CFR §460.82 and PACE Manual Chapter 3 Marketing Guidelines.

A. In HPMS, complete the table below:

<b>RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: MARKETING</b>	<b>YES</b>	<b>NO</b>
1. Applicant agrees to follow PACE Manual Chapter 3 Marketing Guidelines when informing the public about its program and giving prospective participants written information on the following: <ul style="list-style-type: none"> <li>• Description or list of benefits and services;</li> <li>• Description of premiums or other payment responsibilities;</li> <li>and</li> <li>• Other information necessary for prospective participants to make an informed decision about enrollment.</li> </ul>		
2. Applicant agrees that the following information on restriction in services is included in their marketing materials: <ul style="list-style-type: none"> <li>• Participant must receive all needed health care, including primary care and specialist physician services (other than emergency services), from the PACE organization or from an entity authorized by the PACE organization; and</li> <li>• Participants may be fully and personally liable for the costs of unauthorized or out-of-network services.</li> </ul>		

3. Applicant agrees that the marketing material is free of inaccuracies, misleading information, or misrepresentations.		
4. Applicant agrees to make marketing materials available to prospective and current participants in English and other languages specified by the SAA, and in Braille, if necessary.		
5. Applicant agrees to obtain CMS Regional Office approval of all marketing information before distribution.		
6. Applicant agrees that its employees or agents will not use the following prohibited marketing practices: <ul style="list-style-type: none"> <li>• Discrimination of any kind, except that marketing may be directed to individuals eligible for PACE by reason of their age;</li> <li>• Activities that could mislead or confuse potential participants or misrepresent the PACE organization, CMS, or the SAA;</li> <li>• Gifts or payment to induce enrollment;</li> <li>• Contracting outreach efforts to individuals or organizations whose sole responsibility involves direct contact with the elderly to solicit enrollment; and</li> </ul>		
7. Applicant agrees to establish, implement, and maintain a marketing plan with measurable enrollment objectives and a system for tracking effectiveness in accordance with 42 CFR §460.82(f).		
8. Applicant agrees that its employees or agents will not use any marketing practices that are prohibited according to PACE regulation at 42 CFR §460.82.		

B. In the Documents Section, upload marketing materials to be distributed. For website, please include screen shots.

**3.6 Explanation of Rights**

The purpose of this section is to ensure that all PACE applicants have a Participant Bill of Rights, and policies and procedures consistent with the requirements of 42 CFR §460.110, §460.112, §460.116, and §460.118.

A. In HPMS, complete the table below:

<b>RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: EXPLANATION OF RIGHTS</b>	<b>YES</b>	<b>NO</b>
1. Applicant's policies and procedures ensure that the participant, his or her representative, if any, understand their participant rights as specified in 42 CFR §460.110 §460.112, §460.116, and §460.118.		
2. Applicant's policies and procedures ensure that staff (employed and contracted) are educated and understand participant rights as specified in 42 CFR §460.110 §460.112, §460.116, and §460.118.		
3. Applicant agrees to explain the rights to the participant at the time of enrollment in a manner understood by the participant as specified in 42 CFR §460.110(b), §460.112, and §460.116(b).		
4. Applicant agrees to meet the following requirements: <ul style="list-style-type: none"> <li>• Write the participant's rights in English and in any other principal languages of the community; and</li> <li>• Display the participant's rights in a prominent place in the PACE center as specified in 42 CFR §460.116(c)(1)(2).</li> </ul>		
5. Applicant ensures that their procedures respond to and rectify a violation of a participant's rights in 42 CFR §460.118.		
6. Applicant agrees to explain advance directives to participants, and establish them, if the participant so desires, as specified in 42 CFR 460.112(e)(2).		

B. In the Documents Section, upload a copy of your Participant Bill of Rights.

### 3.7 Grievances

The purpose of this section is to ensure that all PACE applicants have a formal written process for participants, their family members or representatives to express dissatisfaction with service delivery or the quality of care furnished consistent with the requirements of 42 CFR §460.120.

A. In HPMS, complete the table below:

<b>YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: GRIEVANCES</b>	<b>YES</b>	<b>NO</b>
1. Applicant agrees to have a formal written process to evaluate and resolve medical and non-medical grievances by participants, their family members, or representatives, that includes the following: <ul style="list-style-type: none"> <li>• How a participant files a grievance;</li> <li>• Documentation of a grievance;</li> <li>• Response to and resolution to a grievance in a timely manner; and</li> <li>• Maintenance of confidentiality of the grievance (see 42 CFR §460.120(c)).</li> </ul>		
2. Applicant agrees to document all expressions of dissatisfaction with service delivery or quality of care furnished, whether written or oral (42 CFR §460.120).		
3. Applicant agrees to provide participants with written information of the grievance process upon enrollment, and annually thereafter (42 CFR §460.120(b)).		
4. Applicant agrees to furnish all required services to participants during the grievance process (42 CFR §460.120(d)).		
5. Applicant agrees to discuss the specific steps that will be taken to resolve the grievance, including timeframes for a response (42 CFR §460.120(e)).		
6. Applicant agrees to maintain, aggregate and analyze information on grievance proceedings, and use this information in the internal QAPI program (42 CFR §460.120(f)).		

B. In the Documents Section, upload a copy of your policy and procedure for grievances.

### 3.8 Appeals

The purpose of this section is to ensure that all PACE applicants have a formal written appeals process consistent with the requirements 42 CFR §460.104, §460.122, and §460.124.

A. In HPMS, complete the table below:

<b>RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: APPEALS</b>	<b>YES</b>	<b>NO</b>
<p>1. Applicant agrees to have a formal written process, with specified timeframes for response, to address non-coverage of or nonpayment of a service, that includes the following as specified in 42 CFR §460.122 (a), and 42 CFR §460.122 (c)(1-6):</p> <ul style="list-style-type: none"> <li>• Written denials of coverage or payment are prepared and processed timely;</li> <li>• How a participant files an appeal;</li> <li>• Documentation of participant's appeal;</li> <li>• Credentialed and impartial third party, not involved in the original action and without a stake in the outcome of the appeal, will be appointed to review the participant's appeal;</li> <li>• Appeals will be responded to and resolved as expeditiously as the participant's health condition requires, but no later than 30 calendar days after the organization receives the appeal; and</li> <li>• Confidentiality of a participant's appeal is maintained.</li> </ul>		
<p>2. Applicant agrees to provide participants written information on the appeals process upon enrollment, annually thereafter, and whenever the interdisciplinary team (IDT) denies a request for services or payment as specified in 42 CFR §460.122(b), and 42 CFR §460.124.</p>		
<p>3. Applicant agrees to appoint an appropriately credentialed impartial third party and give all parties involved in the appeal appropriate written notification and a reasonable opportunity to present evidence related to the dispute in person, and in writing as specified in 42 CFR §460.122(d)(1)(2).</p>		
<p>4. Applicant agrees to furnish the disputed services to Medicaid participants until issuance of the final determination, if the following conditions are met as specified in 42 CFR §460.122(e)(1)(i-ii):</p> <ul style="list-style-type: none"> <li>• The PACE organization is proposing to terminate or reduce services currently being furnished to the participant; and</li> <li>• The participant requests continuation of the service with the understanding that he or she may be liable for the costs of the contested service if the determination is not made in his or her favor.</li> </ul>		

5. Applicant agrees to furnish all other required services to the participant as specified in 42 CFR §460.122(e)(2).		
6. Applicant agrees to furnish the disputed service as expeditiously as the participant's health condition requires, if a determination is made in favor of the participant on appeal as specified in 42 CFR §460.122(g).		
7. Applicant agrees to notify CMS, the SAA and the participant at the time a decision is made that is wholly or partially adverse to the participant as specified in 42 CFR §460.122(h)(1-3).		
8. Applicant agrees to maintain, aggregate and analyze information on appeal proceedings, and use this information in the internal QAPI program as specified in 42 CFR §460.122(i).		
9. Applicant agrees to have an expedited appeals process for situations in which the participant believes that his or her life, health, or ability to regain maximum function could be seriously jeopardized, absent provision of the service in dispute as specified in 42 CFR §460.122(f).		
10. Applicant agrees to respond to an expedited appeal as expeditiously as the participant's health condition requires, but no later than 72 hours after the organization receives the appeal as specified in 42 CFR §460.104(d)(2)(ii), and 42 CFR §460.122(f)(2).		
11. Applicant agrees to make its participants aware that the applicant can extend the 72-hour timeframe for an expedited appeal by up to 14 calendar days for either of the following reasons as specified in 42 CFR §460.104(d)(iii)(A)(B) and 42 CFR §460.122(f)(3)(i-ii): <ul style="list-style-type: none"> <li>• The participant requests the extension; and</li> <li>• The organization justifies to the SAA the need for additional information and how the delay is in the interest of the participant.</li> </ul>		
12. Applicant agrees to do the following as specified in 42 CFR §460.124: <ul style="list-style-type: none"> <li>• Inform a participant in writing of his or her additional appeal rights under Medicare or Medicaid managed care, or both; and</li> <li>• Assist the participant in choosing which external appeal avenue to pursue, and forward the appeal to the appropriate external entity.</li> </ul>		

B. In the Documents Section, upload your policies and procedures for the appeals process.

Note: This process must be developed in accordance with 42 CFR §460.122.

C. In the Documents Section, upload your policies and procedures for informing participants of their additional appeals rights under Medicare and/or Medicaid, including the process for filing further appeals.

Note: Policies and procedures must be developed in accordance with 42 CFR §460.124.

### 3.9 Enrollment

The purpose of this section is to ensure that all PACE applicants enroll participants into the PACE program consistent with the requirements at 42 CFR §460.150, §460.152, §460.154, §460.156, §460.158, and §460.160.

A. In HPMS, complete the table below:

<b>RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: ENROLLMENT</b>	<b>YES</b>	<b>NO</b>
1. Applicant agrees to enroll individuals who meet all of the following eligibility requirements as specified in 42 CFR §460.150(b)(1-4), and 42 CFR §460.150(c)(1)(2): <ul style="list-style-type: none"> <li>• Is 55 years of age or older;</li> <li>• Is determined by the SAA to need the nursing facility services level of care for coverage under the State Medicaid plan;</li> <li>• Resides in the PACE organization service area;</li> <li>• Meets any additional program specific eligibility conditions imposed under the PACE program agreement; and</li> <li>• Able to live in a community setting without jeopardizing his or her health or safety as determined by criteria specified in the program agreement.</li> <li>• PACE enrollee may be, but is not required to be any or all of the following: (1) entitled to Part A, (2) enrolled under Part B, (3) Eligible for Medicaid, (4) private pay.</li> </ul>		
2. Applicant agrees to comply with the requirements of 42 CFR §460.150(d) and not restrict enrollment based on Medicare or Medicaid eligibility.		
3. Applicant agrees that the enrollment agreement minimally includes the requirements as specified in 42 CFR §460.154.		

<p>4. Applicant agrees that the intake process minimally includes the following activities for PACE staff and the potential participant, representative, and/or caregiver as specified in 42 CFR §460.152(a)(1-4):</p> <ul style="list-style-type: none"> <li>• Exhibits and explains each element of the enrollment agreement;</li> <li>• Informs participant that PACE is the sole service provider;</li> <li>• Informs participant that PACE guarantees access to all necessary services, but not access to specific providers;</li> <li>• Provides a list of employed and contracted staff who deliver PACE services;</li> <li>• Discloses required monthly premium if applicable;</li> <li>• Discloses Medicaid spend-down obligations if applicable;</li> <li>• Discloses post-eligibility treatment of income if applicable;</li> <li>• Requires a signed release form for PACE to obtain medical, financial, and Medicare and Medicaid eligibility information;</li> <li>• Requires assessment by the SAA to determine eligibility for nursing facility services (NF) level of care coverage under the State Medicaid Plan; and</li> <li>• Requires assessment by the PACE staff to determine if they can be cared for appropriately in a community setting and that the individual meets all PACE eligibility criteria.</li> </ul> <p>Note: Intake is an intensive process during which PACE staff members make one or more visits to a potential participant's residence and the potential participant makes one or more visits to the PACE center.</p>		
<p>5. Applicant agrees to do the following when enrollment is denied to a prospective participant because his/her health or safety would be jeopardized by living in the community as specified in 42 CFR §460.152(b)(1-4):</p> <ul style="list-style-type: none"> <li>• Notify the individual in writing of the reason for the denial;</li> <li>• Refer the individual to alternative services, as appropriate;</li> <li>• Maintain supporting documentation of the written notification; and</li> <li>• Notify CMS and SAA and make documentation available for review.</li> </ul>		
<p>6. Applicant agrees to give the enrolled participant the following items as specified in 42 CFR §460.156(a)(1-4):</p> <ul style="list-style-type: none"> <li>• A copy of the enrollment agreement;</li> <li>• A PACE membership card;</li> <li>• Emergency information explaining PACE membership and how to access emergency services to post in participant's residence; and</li> <li>• PACE program stickers for Medicare and Medicaid cards that include the PACE phone number.</li> </ul>		

7. Applicant agrees to submit participant information to CMS and SAA in accordance with established procedures as specified in 42 CFR §460.156(b).		
8. Applicant agrees to meet the following requirements when making necessary changes in the enrollment agreement as specified in 42 CFR §460.156(c)(1)(2): <ul style="list-style-type: none"> <li>• Give an updated copy to the participant; and</li> <li>• Explain the changes to the participant, caregiver, or representative in a way they understand.</li> </ul>		
9. Applicant ensures that the effective date for participant enrollment in the PACE program is the first day of the calendar month following the date the PACE organization receives the signed enrollment agreement as specified in 42 CFR §460.158.		
10. Applicant agrees to continue enrollment until the participant's death, regardless of changes in health status, unless either of the following actions occur as specified in 42 CFR §460.160(a)(1)(2): <ul style="list-style-type: none"> <li>• The participant voluntarily disenrolls; or</li> <li>• The participant is involuntarily disenrolled per PACE regulations.</li> </ul>		
11. Applicant agrees to cooperate with the annual SAA reevaluation of the participant's continued need for nursing facility level of care as required under the State Medicaid plan. If the SAA permanently waives the requirement due to SAA determination that there is no reasonable expectation of improvement or significant change in the participant's condition, applicant agrees to maintain documentation of SAA waiver and justification in the participant's medical record as specified in 42 CFR §460.160(b)(1)(i-ii).		
12. Applicant agrees to continue enrollment for the participant who no longer meets the State Medicaid nursing facility level of care, if the SAA deems the participant eligible to continue until the next annual reevaluation because the participant reasonably would be expected to meet the nursing facility level of care requirement within the next 6 months without continued participation in the PACE program as specified in 42 CFR §460.160(b)(2).		
13. Applicant agrees to work in consultation with the SAA in making a determination of deemed continued eligibility as specified in 42 CFR §460.160(b)(3): <ul style="list-style-type: none"> <li>• Use the SAA established criteria for "deemed continued eligibility" which is determined through applying the criteria to a review of the medical record and plan of care; and is specified in the program agreement.</li> </ul>		

B. In the Documents Section, upload policies and procedures for eligibility and enrollment, including the criteria used to determine if individuals are able to live in a community setting without jeopardizing their health or safety.

Note: The policies and procedures for eligibility and enrollment must be developed in accordance with 42 CFR §460.150, §460.152, §460.154, §460.156, §460.158, and §460.160.

C. In the Documents Section, upload any additional enrollment criteria.

Note: -The policies and procedures for eligibility and enrollment must be developed in accordance with 42 CFR §460.150, §460.152, §460.154, §460.156, §460.158, and §460.160.

**3.10 Disenrollment**

The purpose of this section is to ensure that all PACE applicants voluntarily or involuntarily disenroll participants and reinstate them in other Medicare and Medicaid Programs, or the PACE program consistent with the requirements of 42 CFR §460.162 §460.164, §460.166, §460.168, §460.170, and §460.172.

A. In HPMS, complete the table below:

<b>RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: DISENROLLMENT</b>	<b>YES</b>	<b>NO</b>
1. Applicant agrees to meet the following requirements regarding documentation for disenrollment as specified in 42 CFR §460.172(a-c): <ul style="list-style-type: none"> <li>• Have a policy and procedure in place to document the reasons for all voluntary and involuntary disenrollments;</li> <li>• Make documentation available for review by CMS and the SAA; and</li> <li>• Use the internal QAPI program to review documentation on voluntary disenrollment.</li> </ul>		
2. Applicant agrees to execute disenrollment for any participant initiating voluntary disenrollment from the program without cause at any time as specified in 42 CFR §460.162.		

<p>3. Applicant agrees that involuntary disenrollment of a participant will only be initiated for any of the following reasons as specified in 42 CFR §460.164(a)(1-6), and 42 CFR §460.164(b)(1)(2):</p> <ul style="list-style-type: none"> <li>• Participant fails to pay, or to make satisfactory arrangements to pay, any premium due the PACE organization after a 30-day grace period;</li> <li>• 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;</li> <li>• Participant is determined to no longer meet the State Medicaid nursing facility level of care requirements and is no longer deemed eligible;</li> <li>• PACE program agreement with CMS and the SAA is not renewed or is terminated;</li> <li>• PACE organization is unable to offer health care services due to the loss of State licenses or contracts with outside providers;</li> <li>• Participant engages in disruptive or threatening behavior by exhibiting behavior that jeopardizes his or her health or safety, or the safety of others; and</li> <li>• Participant with decision-making capacity refuses to comply with the care plan or terms of the enrollment agreement.</li> </ul>		
<p>4. Applicant agrees to have a policy and procedure that includes documentation requirements for disenrollment of a participant with disruptive or threatening behavior as specified in 42 CFR §460.164(c)(1)(2)that includes:</p> <ul style="list-style-type: none"> <li>• Reason for the proposed involuntary disenrollment; and</li> <li>• Efforts to remedy the situation.</li> </ul>		
<p>5. Applicant agrees not to involuntarily disenroll a participant who engages in non-compliant behavior if the behavior (including repeated non-compliance with medical advice and repeated failure to keep appointments) is related to a mental or physical condition unless the behavior jeopardizes his or her health or safety, or the safety of others as specified in 42 CFR §460.164(d)(1)(2).</p>		
<p>6. Applicant agrees to ensure that before an involuntary disenrollment is effective, the SAA reviewed and determined that the applicant has adequately documented acceptable grounds for disenrollment as specified in 42 CFR §460.164(e).</p>		

<p>7. Applicant agrees to take the following actions in executing the disenrollment as specified in 42 CFR §460.166(a)(1-3), and 42 CFR §460.166(b)(2):</p> <ul style="list-style-type: none"> <li>• Use the most expedient process allowed under Medicare and Medicaid procedures and set forth in the PACE program agreement;</li> <li>• Coordinate the disenrollment date between Medicare and Medicaid (for dual eligible participants);</li> <li>• Give reasonable advance notice to the participant; and</li> <li>• Continue to deliver PACE services to the participant until the date enrollment is terminated.</li> </ul>		
<p>8. Applicant agrees to establish a disenrollment policy and procedure to ensure that the participant is aware they must continue to use PACE services and remain liable for PACE premiums until the disenrollment is effective as specified in 42 CFR §460.166(b)(1).</p>		
<p>9. Applicant agrees to take the following actions to facilitate a participant's reinstatement in other Medicare and Medicaid programs after disenrollment as specified in 42 CFR §460.168(a)(b):</p> <ul style="list-style-type: none"> <li>• Make appropriate referrals and transmit copies of medical records to new providers in a timely manner; and</li> <li>• Work with CMS and SAA to reinstate the participant in other Medicare and Medicaid programs for which the participant is eligible.</li> </ul>		
<p>10. Applicant agrees to permit a previously disenrolled participant to be reinstated in the PACE program as specified in 42 CFR §460.170(a).</p>		
<p>11. Applicant agrees to reinstate a previously disenrolled participant with no break in coverage if the reason for disenrollment is failure to pay the premium, and the participant pays the premium before the effective date of disenrollment as specified in 42 CFR §460.170(b).</p>		

B. In the Documents Section, upload a copy of the Applicant's Voluntary Disenrollment policy and procedure.

C. In the Documents Section, upload a copy of the Involuntary Disenrollment policy and procedure.

**3.11 Personnel Compliance**

The purpose of this section is to ensure that all PACE applicants have a written plan for personnel training and competency compliance that is consistent with the requirements of 42 CFR §460.64, §460.66, §460.68, and §460.71.

A. In HPMS, complete the table below:

<b>RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: PERSONNEL COMPLIANCE</b>	<b>YES</b>	<b>NO</b>
<p>1. Applicant ensures that staff having direct participant contact, (employed and contracted) meet the following conditions as specified in 42 CFR §460.64:</p> <ul style="list-style-type: none"> <li>• Is legally authorized (e.g., currently licensed, registered, or certified if applicable) to practice in the state in which he/she performs the function or action as evidenced by primary verification of licenses or certifications;</li> <li>• Act within the scope of his/her authority to practice;</li> <li>• Has one year of experience with a frail or elderly population;</li> <li>• Meet a standardized set of competencies for the specific position description established by the applicant and approved by CMS prior to working independently; and</li> <li>• Be medically cleared for communicable diseases and have all immunizations up-to-date prior to engaging in direct participant contact.</li> </ul> <p>Note: In addition to the qualifications specified above, applicant ensures that physicians meet the qualifications and conditions in 42 CFR §410.20.</p>		
<p>2. Applicant agrees to provide training to maintain and improve the skills and knowledge of each staff member with respect to the individuals specific duties that results in his or her continued ability to demonstrate the skills necessary for the performance of the position as specified in 42 CFR §460.66(a).</p>		

<p>3. Applicant agrees to develop a training program as specified in 42 CFR §460.66(b) for each personal care attendant to establish the individual's competency on furnishing personal care services and specialized skills associated with specific care needs of individual participants.</p> <p>Personal care attendants must exhibit competency before performing personal care services independently as specified in 42 CFR §460.66(c).</p>		
<p>4. Applicant agrees to provide each staff (employed and contracted) with an orientation that includes the organization's mission, philosophy, policies on participant rights, emergency plan, ethics, the PACE benefit, and any policies related to the job duties of specific staff prior to working independently as specified in 42 CFR §460.71(a)(1).</p>		
<p>5. Applicant agrees to develop a competency evaluation program that identifies those skills, knowledge, and abilities that must be demonstrated by direct participant care staff (employees and contractors) as specified in 42 CFR §460.71(a)(2). Applicant also agrees that the competency program must be evidenced as completed before performing participant care and on an ongoing basis by qualified professionals as specified in 42 CFR §460.71(a)(3).</p>		
<p>6. Applicant agrees to designate a staff member to oversee the orientation and competency evaluation programs for employees and work with the PACE contractor liaison to ensure compliance by contracted staff as specified in 42 CFR §460.71(a)(4).</p>		
<p>7. Applicant ensures that all staff (employed and contracted) furnishing direct participant care services meet the following as specified in 42 CFR §460.71(1)-(6), and</p> <ul style="list-style-type: none"> <li>• Comply with State or Federal requirements for direct patient care staff in their respective settings.</li> <li>• Comply with Requirements of 42 CFR §460.68(a), regarding persons with criminal convictions.</li> <li>• Have verified current certifications or licenses for their respective positions.</li> <li>• Are free of communicable diseases and are up to date with immunizations before performing direct patient care,</li> <li>• Have been oriented to the PACE program, and</li> <li>• Agree to abide by the philosophy, practices, and protocols of the PACE organization.</li> </ul>		

**3.12 Program Integrity**

The purpose of this section is to ensure that all PACE applicants employ individuals or contract with organizations consistent with the requirements of 42 CFR §460.68.

A. In HPMS, complete the table below:

<b>RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: PROGRAM INTEGRITY</b>	<b>YES</b>	<b>NO</b>
1. Applicant agrees to comply with requirements of 42 CFR §460.68 (a) and attests that it will not employ or contract with individuals who have been excluded from participation in the Medicare or Medicaid programs, who have been convicted of criminal offenses related to their involvement in health or social service programs, or in any capacity where an individuals' contact with participants would pose a potential risk because the individual has been convicted of physical, sexual, drug or alcohol abuse.		
2. Applicant agrees to comply with requirements of 42 CFR §460.68(b) regarding identification of members of its governing body or any immediate family member having a direct or indirect interest in contracts, and attests that it will have disclosure and recusal policies and procedures to ensure compliance with 42 CFR §460.68(b) and (c).		

### 3.13 Contracted Services

The purpose of this section is to ensure that all PACE applicants execute contracts consistent with the requirements of 42 CFR §460.70, §460.71, §460.80, §460.98, and §460.100.

A. In HPMS, complete the table below:

<b>RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: CONTRACTED SERVICES</b>	<b>YES</b>	<b>NO</b>
1. Applicant agrees that the organization will have a written contract with each outside organization, agency, or individual that delivers administrative or care-related services not furnished directly by the PACE organization except for emergency services as specified in 42 CFR §460.70(a), and 42 CFR §460.100.		
2. Applicant agrees that the organization will only execute a contract with contractors that meet all applicable Federal and State requirements including, but not limited to the following as specified in 42 CFR §460.70(b)(1)(i-iii), §460.70(b)(2), §460.98, and §460.100: <ul style="list-style-type: none"> <li>• An institutional contractor such as a hospital or skilled nursing facility must meet Medicare or Medicaid participation requirements;</li> <li>• A practitioner or supplier must meet Medicare or Medicaid requirements applicable to the services delivered;</li> <li>• Contractors must comply with the PACE requirements for service delivery, participant rights, and participation in QAPI activities; and</li> <li>• Contractors must be accessible to participants, located either within or near the PACE organization's service area.</li> </ul>		
3. Applicant agrees that the organization designates an official liaison to coordinate activities between contractors and the organization as specified in 42 CFR §460.70(b)(3).		
4. Applicant agrees to maintain a current list of all contractors on file at the PACE center and distribute the list to anyone upon request as specified in 42 CFR §460.70(c).		
5. Applicant agrees to develop an oversight process that the PACE organization will use to ensure that contracts and contractors meet PACE program and Federal requirements, inclusive of being HIPAA compliant.		

6. Applicant agrees that each contract contains the requirements as specified in 42 CFR §460.70(d)(1-5)(i-ix).		
7. Applicant acknowledges it cannot contract with another entity to furnish PACE Center Services until it is fiscally sound as defined in 42 CFR §460.80(a), and has demonstrated competence with the PACE model as evidenced by successful monitoring by CMS and the SAA.		

**3.14 Required Services**

The purpose of this section is to ensure that all PACE applicants have a written plan to furnish care that meets the needs of each participant consistent with the requirements of 42 CFR §460.98, and §460.102.

A. In HPMS, complete the table below:

<b>RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: REQUIRED SERVICES</b>	<b>YES</b>	<b>NO</b>
1. Applicant agrees to provide a PACE benefit package for all participants, regardless of the source of payment as specified in 42 CFR §460.92, that includes the following: <ul style="list-style-type: none"> <li>• All Medicare-covered items and services;</li> <li>• All Medicaid-covered items and services as specified in the State's approved Medicaid plan; and</li> <li>• Other services that the IDT determines are necessary to improve and maintain the participant's overall health status.</li> </ul>		
2. Applicant agrees to provide a PACE benefit package for all participants, regardless of the source of payment as specified in 42 CFR §460.96, that excludes the following: <ul style="list-style-type: none"> <li>• Services not authorized by the IDT, even if a required service, unless it is an emergency service;</li> <li>• Inpatient private room and/or private duty nursing (unless medically necessary) and non-medical items for personal convenience (unless authorized by IDT);</li> <li>• Cosmetic surgery, which does not include surgery that is required for improved functioning of a malformed part of the body resulting from an accidental injury or for reconstruction following mastectomy;</li> <li>• Experimental medical, surgical, or other health procedures; and</li> <li>• Services delivered outside the United States in accordance with regulatory requirements and as permitted under the State's approved Medicaid Plan.</li> </ul>		

### 3.15 Service Delivery

The purpose of this section is to ensure that all PACE applicants have a written plan to furnish care that meets the needs of each participant consistent with the requirements of 42 CFR §460.98, and §460.102.

A. In HPMS, complete the table below:

<b>RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: SERVICE DELIVERY</b>	<b>YES</b>	<b>NO</b>
1. Applicant agrees to establish and implement a written plan to furnish care that meets the needs of each participant in all care settings 24 hours a day, every day of the year as specified in 42 CFR §460.98(a).		
2. Applicant agrees to provide services as specified in 42 CFR §460.98(b)(1-3): <ul style="list-style-type: none"> <li>• Including comprehensive medical, health, and social services that integrate acute and long-term care; and</li> <li>• Are delivered in the PACE center, the participant residence, and inpatient facilities to all participants without discrimination based on race, ethnicity, national origin, religion, sex, age, sexual orientation, mental or physical disability, or source of payment.</li> </ul>		
3. Applicant agrees, at a minimum, to provide the following services as specified in 42 CFR §460.98(c)(1-7): <ul style="list-style-type: none"> <li>• Primary care including physician and nursing services;</li> <li>• Social services;</li> <li>• Restorative therapies including physical therapy and occupational therapy;</li> <li>• Personal care and supportive services;</li> <li>• Nutritional counseling;</li> <li>• Recreational therapy;</li> <li>• Meals; and</li> <li>• Care management by an interdisciplinary care team.</li> </ul>		

<p>4. Applicant agrees to operate at least one PACE center in or contiguous to its defined service area that meet the following conditions as specified in 42 CFR §460.98(d)(1-3) and 42 CFR §460.98(e):</p> <ul style="list-style-type: none"> <li>• Has sufficient capacity to allow routine attendance by participants;</li> <li>• Is accessible and has adequate services to meet the needs of its participants;</li> <li>• Offers the full range of services with sufficient staff to meet the needs of participants at each center if the PACE organization operates more than one center; and</li> <li>• Have participants attend the center as frequently as the IDT determines is necessary based upon the preferences and needs of each participant.</li> </ul>		
<p>5. Applicant agrees to provide each participant primary medical care delivered by a PACE primary care physician as specified in 42 CFR §460.102(c)(1), and 42 CFR §460.102(c)(2)(i-ii) who does the following:</p> <ul style="list-style-type: none"> <li>• Manages the participant's medical situations; and</li> <li>• Oversees the participant's use and provision of care by medical specialists and inpatient facilities.</li> </ul>		

**3.16 Infection Control**

The PACE organization must follow accepted policies and standard procedures with respect to infection control, including at least the standard precautions developed by the Centers for Disease Control and Prevention and PACE applicants have a written plan for infection control that is consistent with the requirements of 42 CFR §460.74.

A. In HPMS, complete the table below:

<b>RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: INFECTION CONTROL</b>	<b>YES</b>	<b>NO</b>
<p>1. PACE applicants have a written plan for infection control that is consistent with the requirements of 42 CFR § 460.74.</p>		
<p>2. Applicant agrees to follow, at a minimum, standard precautions developed by the Centers for Disease Control and Prevention.</p> <p>Note: Refer to the following link: <a href="http://www.cdc.gov">http://www.cdc.gov</a></p>		

<p>3. Applicant agrees to establish, implement and maintain Infection Control Plan that meets the following requirements:</p> <p>(1) Ensures a safe and sanitary environment.</p> <p>(2) Prevents and controls the transmission of disease and infection.</p> <p>(c) Contents of infection control plan. The infection control plan must include, but is not limited to, the following:</p> <p>(1) Procedures to identify, investigate, control, and prevent infections in every PACE center and in each participant's place of residence.</p> <p>(2) Procedures to record any incidents of infection.</p> <p>(3) Procedures to analyze the incidents of infection to identify trends and develop corrective actions related to the reduction of future incidents.</p>		
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**3.17 Interdisciplinary Team**

The purpose of this section is to ensure that all PACE applicants have qualified staff available to support the PACE organization consistent with the requirements of 42 CFR §460.102.

A. In HPMS, complete the table below:

<b>RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: INTERDISCIPLINARY TEAM</b>	<b>YES</b>	<b>NO</b>
<p>1. Applicant ensures that each participant, in order to meet their individual needs, is assigned to and comprehensively assessed by an IDT at the attended PACE center as specified in 42 CFR §460.102(a)(1)(2).</p>		
<p>2. Applicant ensures that the IDT is composed of at least a Primary care physician, Registered nurse, Master's-level social worker, Physical therapist, Occupational therapist, Recreational therapist or activity coordinator, Dietitian, PACE center manager, Home care coordinator, Personal care attendant, Driver or representative as specified in 42 CFR §460.102(b)(1-11).</p>		
<p>3. Applicant ensures that primary medical care is provided by a PACE primary care physician who is responsible for the following as specified in 42 CFR §460.102(c)(1), and 42 CFR §460.102(c)(2)(i-ii):</p> <ul style="list-style-type: none"> <li>• Managing participant medical situations; and</li> <li>• Overseeing the participant use of medical specialists and inpatient care.</li> </ul>		

<p>4. Applicant ensures that the IDT does the following as specified in 42 CFR §460.102(d)(1), §460.102(d)(2)(i-iii), and §460.102(d)(3):</p> <ul style="list-style-type: none"> <li>• Complete initial assessments, periodic reassessments, and plans of care;</li> <li>• Coordinate twenty-four hour care delivery;</li> <li>• Communicates regularly about, and remains alert to, the medical, functional, and psychosocial condition of each participant;</li> <li>• Documents changes of participant's condition in the medical record consistent with documentation policies established by the medical director; and</li> <li>• Serves primarily PACE participants.</li> </ul>		
<p>5. Applicant ensures 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).</p>		

**3.18 Participant Assessment**

The purpose of this section is to ensure that all PACE applicants complete initial comprehensive participant assessments, reassessments, and unscheduled reassessments consistent with requirements of 42 CFR §460.104.

A. In HPMS, complete the table below:

<p><b>RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: PARTICIPANT ASSESSMENT</b></p>	<p><b>YES</b></p>	<p><b>NO</b></p>
<p>1. Applicant ensures that participant assessments are comprehensive, in person, and include, at a minimum (42 CFR §460.104(4)(i-xi)):</p> <ul style="list-style-type: none"> <li>• Physical and cognitive function and ability;</li> <li>• Medication use (prescription, over the counter and alternative medications);</li> <li>• Participant and caregiver preferences for care;</li> <li>• Socialization and availability of family support;</li> <li>• Current health status and treatment needs;</li> <li>• Nutritional status;</li> <li>• Home environment including home access and egress;</li> <li>• Participant behavior;</li> <li>• Psychosocial status;</li> <li>• Medical and dental status; and</li> <li>• Participant language.</li> </ul>		

<p>2. Applicant ensures that each participant receives an initial face-to-face assessment conducted by the following IDT members promptly after enrollment (sometimes these assessments can be done prior to the actual enrollment date):</p> <ul style="list-style-type: none"> <li>• Primary care physician;</li> <li>• Registered nurse;</li> <li>• Master's level social worker;</li> <li>• Physical therapist;</li> <li>• Occupational therapist;</li> <li>• Recreation therapist or activity coordinator;</li> <li>• Dietitian;</li> <li>• Home care coordinator; and</li> <li>• Other healthcare professionals as determined by the IDT. (see 42 CFR §460.104(2)(i-viii))</li> </ul>		
<p>3. Applicant ensures that IDT members conducting the initial assessments promptly consolidate their findings into a single plan of care addressing: problem, intervention, measurable outcomes, staff responsible, outcome met/not met having measurable goals and documented in the participant medical record (42 CFR §460.104(b)).</p>		
<p>4. Applicant ensures that each participant receives a face-to-face reassessment conducted semiannually by the following IDT members or more often if the participant's condition dictates (42 CFR §460.104(c)(1)):</p> <ul style="list-style-type: none"> <li>• Primary care physician;</li> <li>• Registered nurse;</li> <li>• Master's level social worker;</li> <li>• Recreational therapist or activity coordinator; and</li> <li>• Other healthcare professionals as determined by the IDT.</li> </ul>		
<p>5. Applicant ensures that each participant receives a face-to-face reassessment conducted annually by the following IDT members (42 CFR §460.104(c)(2)):</p> <ul style="list-style-type: none"> <li>• Physical therapist;</li> <li>• Occupational therapist;</li> <li>• Dietitian;</li> <li>• Home care coordinator; and</li> <li>• Other healthcare professionals as determined by the IDT.</li> </ul>		

6. Applicant ensures that IDT members conducting reassessments promptly complete the following: <ul style="list-style-type: none"> <li>• Reevaluate the care plan and discuss changes with the IDT and participant/caregiver;</li> <li>• Revise the plan of care and update measurable goals based on IDT and participant approval;</li> <li>• Deliver services identified in the revised care plan; and</li> <li>• Document assessments and any revisions to the plan of care in the participant medical record.</li> </ul>		
7. Applicant ensures that the IDT conducts unscheduled reassessments when there are (42 CFR §460.104(d)(1-2)): <ul style="list-style-type: none"> <li>• Changes in participant health or status or psychosocial status; or</li> <li>• Requests by participants/caregivers for reassessment.</li> </ul>		
8. Applicant ensures that unscheduled reassessments are conducted face-to-face by the applicable IDT member.		
9. Applicant ensures that there are explicit procedures for performance of unscheduled reassessments requested by the participant/caregiver (42 CFR §460.104(d)(2)).		

**3.19 Plan of Care**

The purpose of this section is to ensure that all PACE applicants develop, implement, and evaluate a plan of care for each participant that is consistent with the requirements of 42 CFR §460.106.

A. In HPMS, complete the table below:

<b>RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: PLAN OF CARE</b>	<b>YES</b>	<b>NO</b>
1. Applicant ensures prompt integration of discipline-specific assessments by the IDT into a comprehensive single plan of care for each participant.		
2. Applicant ensures that the plan of care specifies: Participant medical, physical, psychological, and social needs identified during assessment; and <ul style="list-style-type: none"> <li>o Intervention;</li> <li>o Measurable outcomes to be achieved;</li> <li>o Implementation frequency intervention;</li> <li>o Staff responsible; and</li> <li>o Outcome met/not met.</li> </ul>		

3. Applicant ensures that the IDT members coordinate and monitor delivery of all services (direct and contracted & in all settings) prescribed in the care plan.		
4. Applicant ensures that the IDT members continuously update the care plan as participant health status changes and communicate changes to all IDT members (42 CFR §460.106(f)).		
5. Applicant ensures that the IDT reevaluates the goals and measurable outcomes of each participant's care plan at least semiannually.		
6. Applicant ensures that the participant and/or caregiver participate in the development, review, and reevaluation of the care plan (42 CFR §460.106(f)).		
7. Applicant ensures that the IDT provides documentation in the medical record for the following: <ul style="list-style-type: none"> <li>• Original plan of care;</li> <li>• Ongoing changes to the plan of care;</li> <li>• Participant/caregiver preferences and concerns; and</li> <li>• IDT discussion that demonstrates collaborative participation in developing and updating the single comprehensive plan of care.</li> </ul>		

### 3.20 Restraints

The purpose of this section is to ensure that all PACE applicant's comply with the physical and chemical restraint requirements of 42 CFR §460.114.

A. In HPMS, complete the table below:

<b>RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: RESTRAINTS</b>	<b>YES</b>	<b>NO</b>
1. Applicant agrees to use the least restrictive and most effective restraint available.  Note: A restraint may be chemical or physical and is defined in the regulation at 42 CFR §460.114(a)(1)(2).		
2. Applicant agrees to restrict the use of restraints to situations that the IDT determines necessary to ensure the participant's physical safety or the safety of others at 42 CFR §460.114(b).		

3. Applicant ensures that restraints are used for a defined, limited period of time based upon the assessment needs of the participant in accordance with safe and appropriate restraining techniques after other less restrictive measures have been found to be ineffective to protect the participant or others from harm, and are removed or ended at the earliest possible time.		
4. Applicant ensures that the condition of the restrained participant is continually assessed, monitored and reevaluated at 42 CFR §460.114(c).		

**3.21 Physical Environment**

The purpose of this section is to ensure that all PACE applicants provide a safely designed PACE center and maintain equipment consistent with the requirements of 42 CFR §460.72.

A. In HPMS, complete the table below:

<b>RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: PHYSICAL ENVIRONMENT</b>	<b>YES</b>	<b>NO</b>
1. Applicant ensures a PACE center which: <ul style="list-style-type: none"> <li>• Is designed, constructed, equipped, and maintained to provide physical safety for participants, personnel, and visitors; and</li> <li>• Provides a safe, sanitary, functional, accessible, and comfortable environment for the delivery of services and preservation of participant dignity and privacy at 42 CFR §460.72 (a)(i-ii).</li> </ul>		
2. Applicant ensures that suitable space and equipment exist to provide the following: <ul style="list-style-type: none"> <li>• Primary medical care and treatment;</li> <li>• Therapeutic recreation;</li> <li>• Team meetings;</li> <li>• Restorative therapies;</li> <li>• Personal care;</li> <li>• Socialization activities; and</li> <li>• Dining services at 42 CFR §460.72 (a)(2).</li> </ul>		
3. Applicant ensures that all equipment is maintained according to manufacturer's recommendations at 42 CFR §460.72 (a)(3)(i).		

<p>4. Applicant ensures the PACE center meets the occupancy provisions of the 2000 edition of the National Fire Protection Association's Life Safety Code that apply to the type of setting in which the center is located.</p> <p>Note: Exceptions are specified in 42 CFR §460.72(b)(1-5).</p>		
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**3.22 Emergency and Disaster Preparedness**

The purpose of this section is to ensure that all PACE applicants have written plans for medical and nonmedical emergency care and disaster response that are consistent with the requirements of 42 CFR §460.72, and §460.100.

A. In HPMS, complete the table below:

<b>RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: EMERGENCY AND DISASTER PREPAREDNESS</b>	<b>YES</b>	<b>NO</b>
<p>1. Applicant ensures availability of emergency equipment at each center as specified in 42 CFR §460.72(c)(4) which includes the following:</p> <ul style="list-style-type: none"> <li>• Portable oxygen;</li> <li>• Airways;</li> <li>• Suction; and</li> <li>• Emergency drugs.</li> </ul>		
<p>2. Applicant ensures that all staff knows how to use the emergency equipment. Every site must have available and ready for immediate use the emergency equipment.</p>		
<p>3. Applicant ensures testing, evaluating and documenting of the effectiveness of emergency and disaster plans at least annually as specified in 42 CFR §460.72(c)(5).</p>		
<p>4. Applicant ensures that the emergency plan holds harmless CMS, the State, and the PACE participant if the PACE organization does not pay for emergency services as specified in 42 CFR §460.100(a).</p>		
<p>5. Applicant agrees to provide for emergency services, inpatient and outpatient settings by a qualified emergency services provider, or one of its contract providers, either in or out of the PACE organization's service area in order to evaluate or stabilize an emergency medical condition as specified in 42 CFR § 460.100(a)(1)(2).</p>		

6. Applicant ensures that the participant and/or caregiver understand when and how to get emergency care, and that no prior authorization is required as specified in 42 CFR §460.100(d).		
7. Applicant agrees to provide access to on-call providers 24-hours a day to consult about emergency services as specified in 42 CFR §460.100(e)(1).		
8. Applicant agrees to provide authorization of urgently needed out-of-network services and post-stabilization care services following emergency services and provide coverage when services are pre-approved by the PACE organization, the PACE organization cannot be contacted, or the PACE organization did not respond to a request for approval within 1 hour after being contacted as specified in 42 CFR §460.100(2)(i)(ii).		

### 3.23 Transportation Services

The purpose of this section is to ensure that all PACE applicants provide safe and accessible transportation consistent with the requirements of 42 CFR §460.76.

A. In HPMS, complete the table below:

<b>RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: TRANSPORTATION SERVICES</b>	<b>YES</b>	<b>NO</b>
1. Applicant agrees to provide safe, properly-equipped, and accessible transportation services to meet the needs of the participant population at 42 CFR §460.76(a).		
2. Applicant agrees to maintain the transportation vehicles it owns, rents, or leases in accordance with the manufacturer's recommendations at 42 CFR §460.76(b)(1).		
3. Applicant ensures that if the transportation services are provided by a contractor, the vehicles are maintained in accordance with the manufacturer's recommendations at 42 CFR §460.76(b)(1).		
4. Applicant ensures that all transportation vehicles are equipped with an operable hands free device to communicate with the PACE center and notify staff when relevant changes in a participant's health status occur at 42 CFR §460.76(c).		
5. Applicant ensures that all transportation personnel (employed and contracted) receive an initial orientation and periodic refresher training to manage participant special needs and emergency situations at 42 CFR §460.76(d)(1-2).		

6. Applicant agrees, that as part of the IDT process, PACE organization staff (employees and contractors) must communicate information and relevant changes in a participant's care plan to transportation personnel including, but not limited to, advance directives at 42 CFR §460.76(e).		
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**3.24 Dietary Services**

The purpose of this section is to ensure that all PACE applicants provide meals that meet the participant's daily nutritional and special dietary needs consistent with the requirements of 42 CFR §460.78.

A. In HPMS, complete the table below:

<b>RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: DIETARY SERVICES</b>	<b>YES</b>	<b>NO</b>
1. Applicant ensures that meals are nourishing, palatable, well-balanced, meet recommended daily nutritional content (RDA), and meet the participant's daily nutritional and special dietary needs as documented in the participant's assessment and care plan at 42 CFR §460.78(a).		
2. Each meal must meet the following requirements consistent with the requirements of 42 CFR §460.78 (a)(i-iii): be prepared by methods that conserve nutritive value, flavor and appearance; be prepared in a form designed to meet individual needs; and be prepared and served at the proper temperature.		
3. Applicant agrees to provide substitute foods or nutritional supplements that meet the daily nutritional and special dietary needs of any participant who refuses or cannot tolerate the food served, or does not eat adequately at 42 CFR §460.76(a)(2).		
4. Applicant agrees to provide nutritional support based on participant condition or diagnosis and physician orders which include: <ul style="list-style-type: none"> <li>• Tube feedings;</li> <li>• Total parenteral nutrition; and</li> <li>• Peripheral parenteral nutrition at 42 CFR §460.78(a)(3).</li> </ul>		

5. Applicant agrees to procure foods (including nutritional supplements and nutrition support items) from sources approved, or considered satisfactory by Federal, State, Tribal or local authorities with jurisdiction over the service area of the organization. Applicant also agrees to store, prepare, distribute and serve foods (including nutritional supplements and nutrition support items) and dispose of food under safe and sanitary conditions.		
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**3.25 Terminations**

The purpose of this section is to ensure that all PACE applicants have a detailed written plan for phase-down in the event of termination consistent with the requirements of 42 CFR §460.50, §460.52, and §460.210.

A. In HPMS, complete the table below:

<b>RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: TERMINATIONS</b>	<b>YES</b>	<b>NO</b>
1. Applicant agrees that the following are notified in advance of termination as specified in 42 CFR §460.50(1)(2): <ul style="list-style-type: none"> <li>• Ninety day advance notice to CMS and the SAA; and</li> <li>• Sixty day advance notice to the participant.</li> </ul>		
2. Applicant agrees to notify the following of termination and transition procedures in writing as specified in 42 CFR §460.52(1): <ul style="list-style-type: none"> <li>• CMS;</li> <li>• SAA;</li> <li>• Community; and</li> <li>• Participant.</li> </ul>		
3. Applicant ensures a process to assist participants with the following as specified in 42 CFR §460.52(2-4): <ul style="list-style-type: none"> <li>• Obtaining reinstatement of conventional Medicare and Medicaid benefits when terminating;</li> <li>• Transferring participant care to other providers when terminating; and</li> <li>• Terminating marketing and enrollment activities.</li> </ul>		
4. Applicant agrees to supply new providers the participant medical records, which meet the required elements in 42 CFR §460.210, during the process of terminating the PACE program agreement as specified in 42 CFR §460.52(b).		

5. Applicant agrees to refer each participant to transitional care when the PACE program agreement is in the process of being terminated as specified in 42 CFR §460.52(b).		
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B. In the documents sections, upload your termination plan.

Note: The plan for termination must be developed in accordance with 42 CFR §460.50, §460.52, and §460.210.

**3.26 Maintenance of Records & Reporting Data**

The purpose of this section is to ensure that all PACE applicants maintain records and submit reports consistent with the requirements of 42 CFR §460.200.

A. In HPMS, complete the table below:

<b>RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: MAINTENANCE OF RECORDS &amp; REPORTING DATA</b>	<b>YES</b>	<b>NO</b>
1. Applicant ensures data collection, record maintenance, and report submission as required by CMS and the State at 42 CFR §460.200(a).  Note: Reports include those necessary for CMS and the State to monitor the operation, cost, quality, effectiveness of the program, and establish payment rates.		
Applicant ensures CMS and SAA access to data and records including, 2. but not limited to: <ul style="list-style-type: none"> <li>• Participant health outcome data;</li> <li>• Financial books and records;</li> <li>• Medical records; and</li> <li>• Personnel records at 42 CFR §460.200(b).</li> </ul>		
2. Applicant ensures policies and procedures to safeguard data, books and records against the following: <ul style="list-style-type: none"> <li>• Loss;</li> <li>• Destruction;</li> <li>• Unauthorized use; and</li> <li>• Inappropriate alteration at 42 CFR §460.200(d).</li> </ul>		

<p>3. Applicant ensures confidentiality of health information through policies and procedures that do the following:</p> <ul style="list-style-type: none"> <li>• Safeguard privacy and confidentiality of participant health information, including mental health information, per HIPAA and other Federal and State laws;</li> <li>• Maintain complete records in an accurate and timely manner; and</li> <li>• Provide participants timely access to review and copy their own medical records as well as request amendments to the record at 42 CFR §460.200(e)(1-4).</li> </ul>		
<p>4. Applicant ensures retention of records for the longest of the following periods:</p> <ul style="list-style-type: none"> <li>• Time specified in State law;</li> <li>• Six years from the last entry date in the record or for medical records of disenrolled participants, 6 years after the date of disenrollment;</li> <li>• Completion of litigation requiring specified health information; and</li> <li>• Resolution of claims or audit findings at 42 CFR §460.200(f)(i-iii).</li> </ul>		

**3.27 Medical Records**

The purpose of this section is to ensure that all PACE applicants maintain medical records in accordance with accepted professional standards consistent with the requirements of 42 CFR §460.210.

A. In HPMS, complete the table below:

<b>RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: MEDICAL RECORDS</b>	<b>YES</b>	<b>NO</b>
<p>1. Applicant agrees to maintain a single, comprehensive medical record for each participant at (42 CFR §460.210(a)).</p>		

<p>2. Applicant ensures that the health information management policy has procedures that govern the maintenance of a single comprehensive medical record for each participant that is:</p> <ul style="list-style-type: none"> <li>• Complete regardless of format (electronic or print);</li> <li>• Accurately documented;</li> <li>• Readily accessible to authorized personnel;</li> <li>• Systematically organized to facilitate review;</li> <li>• Available to employed or contracted staff; and</li> <li>• Maintained and housed at the PACE center where the participant receives services.</li> </ul>		
<p>3. Applicant agrees to promptly transfer copies of pertinent medical record information to all providers delivering direct care in other healthcare settings per HIPAA laws at 42 CFR §460.210(c).</p>		
<p>4. Applicant's medical records are appropriately authenticated by ensuring the following:</p> <ul style="list-style-type: none"> <li>• All entries must be legible, clear, complete, and appropriately authenticated and dated; and</li> <li>• Authentication must include signatures or a secured computer entry by a unique identifier of the primary author who has reviewed and approved the entry at 42 CFR §460.210(d)(1-2).</li> </ul>		

**3.28 Quality Assessment Performance Improvement Program (QAPI)**

The purpose of this section is to ensure that all PACE applicants maintain medical records in accordance with accepted professional standards consistent with the requirements of 42 CFR §460.210.

A. In HPMS, complete the table below:

<b>RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: MEDICAL RECORDS</b>	<b>YES</b>	<b>NO</b>
<p>1. Applicant agrees to do the following as specified in 42 CFR §460.130(a-c):</p> <ul style="list-style-type: none"> <li>• Develop, implement, maintain and evaluate a QAPI program;</li> <li>• Reflect the full range of services furnished by the PACE organization; and</li> <li>• Take action resulting in improvements in its performance in all types of care.</li> </ul>		

<p>2. Applicant agrees to use data collected through the health information system to identify areas for improvement in the delivery of services, quality, and safety across care domains (PACE center, home, inpatient, outpatient, rehabilitative etc.) as specified in 42 CFR §460.136-(a)(1-5) by doing the following:</p> <ul style="list-style-type: none"> <li>• Using a set of outcome measures to identify areas of good or problematic performance;</li> <li>• Taking actions targeted at maintaining or improving care based on outcome measures;</li> <li>• Incorporating improvements into standard practice to sustain performance;</li> <li>• Prioritizing performance improvement activities based on clinical outcomes, prevalence of the problem in the PACE population, and severity of the problem; and</li> <li>• Immediately correcting an identified problem that directly or potentially threatens the health or safety of participants.</li> </ul>		
<p>3. Applicant agrees that the designated QAPI coordinator will do the following as specified in 42 CFR §460.136(b) and §460.136(c)(2):</p> <ul style="list-style-type: none"> <li>• Coordinate and oversee implementation of the QAPI activities; and</li> <li>• Encourage PACE participants and caregivers to participate in QAPI activities, including providing information about their satisfaction with services.</li> </ul>		
<p>4. Applicant ensures that the IDT, PACE staff, and contract providers are involved in the development and implementation of QAPI activities and are aware of the results of these activities as specified in 42 CFR §460.136(c)(1).</p>		
<p>5. Applicant agrees to have one or more committees with community input to do the following as specified in 42 CFR §460.138(a-c):</p> <ul style="list-style-type: none"> <li>• Evaluate outcome data measuring quality performance;</li> <li>• Address the implementation of the QAPI plan and the results from quality improvement activities; and</li> <li>• Provide input related to ethical decision-making on issues such as end-of-life, participant self-determination, and other participant health rights and concerns.</li> </ul>		
<p>6. Applicant agrees to meet the external quality assessment and reporting requirements specified by oversight agencies including, but not limited to, CMS and the SAA by using the established health information system as specified in 42 CFR §460.140.</p>		

7. Applicant agrees to submit, upon request from CMS and/or SAA, data to monitor its operations, costs, quality, and effectiveness of care as specified in 42 CFR §460.200(c).		
8. Applicant ensures a health information system to collect, analyze, integrate, and report data to measure the organization's performance as specified in 42 CFR §460.202(a).		
9. Applicant agrees to submit to CMS all monitoring data elements specified in the PACE program agreement to be reported quarterly or seasonally through the CMS Health Plan Management System (HPMS) as specified in 42 CFR §460.202(b).		
10. Applicant ensures a written QAPI plan as specified in 42 CFR §460.132.		

- B. In the Documents Section, provide a copy of the HPMS data monitoring elements as specified in 42 CFR §460.202(b).
- C. In the Documents Section, upload a copy of the applicant’s QAPI plan.

Note: The QAPI plan must be developed in accordance with 42 CFR §460.132.

**3.29 State Attestations**

- A. The purpose of this section is to ensure that the state is willing to enter into a PACE program agreement with the applying entity, and that it has processes in place to ensure compliance with its obligations under the program (42 CFR §460.12 (b)).
- B. In the document section upload the State Assurances document signed by an authorized official from the State agency responsible for administering the PACE program agreement.

Note: The document should include the written name and title of the official and the name of the State agency.

- C. In the document section upload the state’s Medicaid capitation payment amount as described in 42 CFR §460.182.

Note: If more than one capitation payment is applicable, please identify by cohort.

- D. In the document section upload a description of the state's procedures for the enrollment and disenrollment of participants into the state system, including procedures for any adjustment to account for the difference between the estimated number of participants on which the prospective monthly payment was based and the actual number of participants in that month as required at 42 CFR §460.182(d).

**3.30 Waivers**

PACE organizations are permitted to submit waiver requests as part of their initial application consistent with 42 CFR §460.26 and 42 CFR §460.28.

A. In HPMS, complete the table below:

<b>RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: WAIVERS</b>	<b>YES</b>	<b>NO</b>
Applicant is requesting specific modifications or waivers of certain regulatory provisions as part of this application as permitted under Section 903 of the Benefits Improvement and Protection Act (BIPA) of 2000.		

B. If you are submitting a waiver request with your application, please upload a copy of your waiver request, in the Documents section. Your request should include: Identification of the regulatory section the applicant is requesting to have waived; the rationale behind the waiver request; and if applicable, process(es), policies and procedures that will be followed to ensure participant care is not compromised.

**3.31 Application Attestations**

A. Applicants are required to submit an attestation about the information and statements in their application.

B. Please upload your application attestation document

**3.32 State Readiness Review**

A. Applicants are required to submit a State Readiness Review of their PACE center.

B. Please upload your State Readiness Review.

## **4 Document Upload Templates**

### **4.1 Governing Body**

#### APPENDIX A: NAMES AND CONTACT LIST

1. Name of Program Director:

Telephone Number:

E-mail address:

2. Name of Governing Body/Board of Director contact person:

Telephone Number:

3. Governing Body/Board of Directors:

**4.2 Subordinated Debt**

**PACE Organization Attestation of Subordinated Debt Arrangement**

Contract Number: H\_\_\_\_\_

I attest that <INSERT NAME OF PACE ORGANIZATION> has a subordinated debt arrangement with another entity. Description of Subordinated Debt Arrangement: (If not enough space, please describe on a separate sheet of paper.)

Amount:

Arrangement with:

Contact Name:

Telephone Number:

E-mail:

Period:     /    /     to     /    /20\_\_

Misc. Comments:

### 4.3 State Assurance Signature Pages

[Template for State Assurances]

The purpose of this section is to ensure that the state is willing to enter into a PACE program agreement with the entity, and that it has processes in place to ensure compliance with its obligations under the program. Please upload the following assurances with all blanks filled in and with the appropriate signature from the State Administering Agency.

State certifies that the entity described in this application is qualified to be a PACE provider.

State has elected PACE as part of its Medicaid State Plan which allows for operation of the applicant within the state.

State of \_\_\_\_\_ is willing to enter into a program agreement with the applicant.

State certifies that this PACE Organization will have an enrollment limit of \_\_\_\_\_ participants (if state enrollment limit applies).

State agrees to establish a process to ensure that all potential participants, including any individual who is not eligible for Medicaid, are assessed to determine that he or she needs the level of care required under the state Medicaid plan for coverage of nursing facility services. 460.152(a)(3)

State agrees to establish a process to receive participant enrollment information from the applicant for purpose of enrollment of Medicaid participants into the program. 460.156 (b)  
State agrees to establish a process to ensure that at least annually, the participants will be evaluated to determine if the participant continues to need the level of care required under the State Medicaid plan for coverage of nursing facility services. 460.160(b)

State agrees to establish a process that may permanent waive the annual recertification requirement for a participant if it determines that there is no reasonable expectation of improvement or significant change in the participant's condition because of the severity of a chronic condition or the degree of impairment of functional capacity.

When the state determines a PACE participant no longer meets the State Medicaid nursing facility level of care requirements, The State agrees to establish a process that may deem participants to be eligible to continue to be eligible for PACE under the next annual reevaluation, if in the absence of continued coverage under the program, the participant reasonably would be expected to meet the nursing facility level of care requirement within the next 6 months.

The State agrees to establish criteria to use in making the determination of deemed continued eligibility.

The state agrees to make a determination of continued eligibility in consultation with the applicant, based on a review of the participant's medical record and plan of care.

The state agrees to oversee the applicant's administration of the criteria for determining if a potential PACE enrollee is safe to live in the community.

State agrees to establish a process to ensure that beneficiaries have access the State's Fair Hearings process as an external appeal avenue.

State agrees that before an involuntary disenrollment is effective the State administering agency will review documentation and determining in a timely manner that the applicant has adequately documented acceptable grounds for disenrollment. 460.164(e)

State agrees to establish a process to receive participant disenrollment information for purposes of coordinating the disenrollment date between Medicaid and Medicaid. 460.166

State agrees to ensure that it will work with CMS and the applicant to reinstate a disenrolled participant in other Medicaid programs for which the participant is eligible. 460.168

State agrees to make a prospective monthly payment to the applicant of a capitation amount for each participant. 460.182

State agrees to ensure that the capitation amount:

- is less than what would otherwise have been paid under the state plan if the participants were not in rolled in PACE
- Takes into account the comparative frailty of PACE participants
- Is a fixed amount regardless of changes in the participant's health status

State agrees to establish procedures for the enrollment and disenrollment of participants in the SAA's system, including procedures for any adjustment to account for the difference between the estimated number of participants on which the prospective monthly payment was based, and the actual number of participants in that month.

State agrees to cooperate with CMS in oversight and monitoring of the operations of the applicant's program to ensure compliance with PACE requirements. 460.190 and 460.192

State ensures that it will ensure that the Medicare benefit requirements are protected for dually eligible PACE participants upon entering a facility, in accordance with section 460.90, including details on when and how Medicaid share of cost requirements are imposed.

State certifies that the State Administering Agency will verify that the PACE Organization has qualified administrative and clinical staff employed or under contract prior to furnishing services to participants.

---

Printed name and title

Signature

Date

#### **4.4 State Medicaid Capitation Payment**

[Appendix M Template]

CMS makes a prospective monthly payment to the PACE organization of a capitation amount for each Medicare participant in the payment area. Prospective payments are made up of the pre-ACA county rate, unadjusted for Indirect Medical Education (IME), and multiplied by the sum of the individual risk score and the organization frailty score. This payment methodology is described in the PACE program agreement. We have provided a brief description of PACE payment and the differences between PACE payment and payment for other Medicare Advantage plans below.

##### County Rates

The prospective payment rates for PACE are based on the applicable amount under section 1853(k)(1) of the Act, unadjusted for IME. The applicable amount is the pre-Affordable Care Act rate, which will be phased-out under the Affordable Care Act for other Medicare Advantage plans. The applicable amount will not be phased out for PACE. In rebasing years, this rate is the greater of: 1) the county's FFS rate for the payment year or 2) the prior year's applicable amount increased by the payment year's National Per Capita Medicare Advantage Growth Percentage. In non-rebasing years, this rate is the prior year's applicable amount increased by the payment year's National Per Capita Medicare Advantage Growth Percentage.

Section 1853 (k) (4) of the Act requires CMS to phase out indirect medical education (IME) amounts from MA capitation rates. PACE programs are excluded from the IME payment phase out under that section.

Effective CY 2006 and subsequent years, CMS makes advance monthly per capita payments for aged and disabled enrollees based on the bidding methodology established by the MMA. PACE plans are not required to bid, however.

##### Risk Adjustment

For the final payment rate, the county rate for the PACE organization is multiplied by the individual participant risk score. Risk adjustment allows CMS to pay plans for the risk of the beneficiaries they enroll, instead of an average amount for Medicare beneficiaries. The individual participant risk score for Medicare Advantage and PACE is calculated using the CMS-HCC model (community, long-term institutionalized, End-Stage Renal Disease (ESRD) or new enrollee) published in the Announcement of Calendar Year (CY) 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (Rate Announcement).

A frailty factor is added to each individual's risk score for PACE plan payment. Risk adjustment predicts (or explains) the future Medicare expenditures of individuals based on diagnoses and demographics. But risk adjustment may not explain all of the variation in expenditures for frail community populations. The purpose of frailty adjustment is to predict the Medicare expenditures of community populations with functional impairments that are unexplained by risk

adjustment. The frailty score added to the beneficiary's risk score is calculated at the contract-level, using the aggregate counts of ADLs among HOS-M survey respondents enrolled in a specific organization. More information regarding the HOS-M can be found in section 10.3.1.3. Because the CMS-HCC model has been designed to pay appropriately for the long-term institutionalized population, frailty adjustments are added to the risk scores only for community-based and short-term institutionalized enrollees (i.e., the frailty adjustment for long-term institutionalized enrollees is zero). Updated frailty factors are published in the Rate Announcement for the payment year in which they are first used.

### Additional Information

For additional, more detailed information about PACE Medicare payment, please see the following documents:

- Payments to Medicare Advantage Organizations, Chapter 8, Medicare Managed Care Manual
- Risk Adjustment, Chapter 7, Medicare Managed Care Manual
- CMS publishes changes to the Medicare Advantage payment methodologies in the Advance Notice of Methodological Changes for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (Advance Notice) in mid-February at <http://www.cms.gov/MedicareAdvtgSpecRateStats/> for public comment. The final payment methodologies are published in the Announcement of Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (Rate Announcement) on the first Monday in April at the same website.

### Medicare Part D:

In order for PACE organizations to continue to meet the statutory requirement of providing prescription drug coverage to their enrollees, and to ensure that they receive adequate payment for the provision of Part D drugs, beginning January 1, 2006, PACE organizations began to offer qualified prescription drug coverage to their enrollees who are Part D eligible individuals. The MMA did not impact the manner in which PACE organizations are paid for the provision of outpatient prescription drugs to non-part D eligible PACE participants.

PACE organizations are required to annually submit two Part D bids: one for a Plan Benefit Package (PBP) for dually eligible enrollees and one for a PBP for Medicare-only enrollees. The Part D payment to PACE organizations comprises several pieces, including the direct subsidy, reinsurance payments, and risk sharing. Payments for eligible enrollees of either PBP will include a low-income premium subsidy and a low-income cost-sharing subsidy for basic Part D benefits. Payments for dually eligible enrollees will also include an additional amount to cover nominal cost sharing amounts ("2% capitation"), and an additional premium payment in situations where the PACE plan's basic Part D beneficiary premium is greater than the regional low-income premium subsidy amount.

[Insert PACE rates into chart]

Description of Rate (ex. Dual Eligible, Medicaid Only)

Amount of Rate

Description of Rate (ex. Dual Eligible, Medicaid Only)	Amount of Rate

**4.5 State Continued Eligibility SOP**

[Appendix P Template]

Please provide a description of the criteria the state will use for deemed continued eligibility:

**4.6 State Enrollment and Disenrollment SOP**

[Appendix N Template]

Please provide a description of the State's procedures for the enrollment and disenrollment of participants into the state system, including procedures for any adjustment to account for the difference between the estimated number of participants on which the prospective monthly payment was based and the actual number of participants in that month as required at 460.782(d).

**4.7 Applicant Attestations**

<b>CENTERS FOR MEDICARE AND MEDICAID SERVICES            CENTER FOR BENEFICIARY CHOICES            CENTER FOR MEDICAID AND STATE OPERATIONS            PROVIDER APPLICATION            PROGRAM OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)</b>	
NAME OF LEGAL ENTITY  TRADE NAME (if different)	MAILING ADDRESS
TELEPHONE NUMBER & EXTENSION	FAX
CEO OR EXECUTIVE DIRECTOR: NAME AND TITLE  TELEPHONE NUMBER	MAILING ADDRESS
APPLICANT CONTACT PERSON: NAME TITLE ADDRESS  E-MAIL FAX TELEPHONE NUMBER	
I certify that all information and statements made in this application are true, complete, and current to the best of my knowledge and belief and are made in good faith.	
Signature, CEO / Executive Director	Date



**4.8 State Readiness Review**

**READINESS REVIEW  
FINDINGS AND COMPLIANCE  
REPORT**

PAGE ORGANIZATION:

DATE (S) OF REVIEW:

REVIEWER (S) – NAME, TITLE AND DEPARTMENT:

SUMMARY OF FINDINGS (SITE ONLY THOSE AREAS NOT MET):

ORGANIZATION'S COMPLIANCE PLAN:

CHANGES MADE THAT BROUGHT ORGANIZATION INTO COMPLIANCE:

PACE ORGANIZATION'S READINESS REVIEW COMPLETE  
ORGANIZATION HAS MET ALL ON-SITE REVIEW CRITERIA

DATE OF COMPLETION:

STATE ADMINISTERING AGENCY:

SAA REPRESENTATIVE SIGNATURE:

## STATE READINESS REVIEW

In developing the application process for potential PACE providers, States expressed concern on the feasibility of requiring an entity to be operational at the time of application. The State representatives maintained that potential PACE sites need approval by CMS as a PACE provider before the site is able to market its program and begin to enroll participants. Absent CMS approval of a site as a PACE provider, the entity has no authority to enroll participants, provide PACE services or receive payment.

As an alternative for sites that are not operational at the time of application, the States recommended that CMS only approve applications from potential PACE organizations that satisfy Federal requirements and have met the requirements of a State Readiness Review (SRR). The SRR is performed by the State at the applicant's site. At the time of the SRR, the entity will not be operational and thus will have no enrolled participants. The purpose of this review is to determine the organization's readiness to administer the PACE program and enroll participants. The SRR will include a minimum set of criteria established by CMS in conjunction with the States. The States are free to add any additional criteria to the 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 regulation; and 3) has established the contracts necessary to provide all-inclusive, quality care to its participants.

The SRR will focus on a wide variety of areas, including evidence of the site's policies and procedures, the design and construction of the building, emergency preparedness, the site's compliance with OSHA, FDA, State and local laws, and adherence life safety codes. There are several areas of the SRR that defer to state and local laws and regulations for compliance. If the applicant's state has more stringent laws and regulations, those laws will apply in place of the federal requirement. However, it is incumbent upon the SRR team to ensure that their state laws or regulations encompass each of the items identified in the federal requirement.

This program recognizes the unique partnership with the States for implementation of the PACE program and the substantial financial commitment States have with PACE organizations. Experience has shown that States are extremely active in the PACE program. States will play a significant role in selecting appropriate organizations, developing the PACE programs in the SRR process, and monitoring PACE organizations. Even though CMS will not conduct the SRR, we may accompany the States on the readiness review to provide technical assistance in order to assure compliance with federal standards.

Upon completion of the SRR, the State will be responsible for preparing and submitting a report of their findings to CMS. Each time a readiness review is conducted, the State will submit a copy of the completed readiness review, a report that explains the State's review process, and any additional review criteria that were utilized. If the applicant meets all of the criteria in the readiness review, the State will submit a brief report to CMS on its findings.

If the applicant does not meet all of the established criteria, the State, in conjunction with the applicant, will develop an initial compliance plan to bring the applicant into compliance. This plan will outline both the unmet criteria and the plan of correction. We have chosen to not specify a timeframe for completion of the initial compliance plan to provide both the State and the applicant with flexibility in meeting the requirements in the SRR. However, we do not anticipate that completion of the initial compliance plan will take an extended period of time since the applicants should be ready to enroll participants at the time of the SRR. Once the initial compliance plan has been completed to the satisfaction of the State, the review team will submit a complete report to CMS. The report will include an explanation of the State's review process, any additional review criteria that were utilized, the list of unmet criteria, the reason the applicant failed to meet the criteria, the initial compliance plan, and an explanation of the changes that were made to bring the applicant into compliance with the requirements.

## PROPOSED FORMAT FOR THE READINESS REVIEW

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
PHYSICAL ENVIRONMENT (§460.72)			
<p>I.A. The PACE center must be designed, constructed, equipped, and maintained to provide for the physical safety of participants, personnel, and visitors.</p>	<p>EVIDENCE OF COMPLIANCE WITH ALL STATE AND LOCAL BUILDING, FIRE SAFETY AND HEALTH CODES.</p> <p>Evidence of the following:</p> <ul style="list-style-type: none"> <li>• Fire exit system</li> <li>• Doorways that provide adequate width to allow easy access and movement of participants by wheelchair or stretcher;</li> <li>• Doorways and stairways that provide access free from obstructions at all times;</li> <li>• Lights and handrails in stairways, corridors, bathrooms, and at exits used by participants;</li> <li>• Toilets and stalls in the public bathrooms that are accessible to allow use by nonambulatory and handicapped participants, staff and visitors;</li> <li>• Evidence of compliance with the ADA (28 CFR Part 36 Title</li> </ul>	<p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p>	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	<p>III).</p> <ul style="list-style-type: none"> <li>• Facility equipped with call lights for a communication system that alerts staff of participant problems in bathrooms, therapy areas, etc.</li> <li>• Design features to safeguard cognitively impaired clients who may wander (e.g. fences, door alarms, detector bracelets, etc.)</li> <li>• Written plan that outlines scheduled maintenance for the PACE center to include building maintenance</li> </ul> <p>OTHER (SPECIFY)</p>	<input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> Other (Specify and Attach)	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
<p>I. B. The PACE center must ensure a safe, functional, accessible and comfortable environment for the delivery of services to the participant.</p>	<p>EVIDENCE OF CERTIFICATION OR LICENSURE BY THE STATE OR A RECOGNIZED ENTITY FOR ADULT DAY CENTERS THAT ENCOMPASSES APPROPRIATE CRITERIA.</p> <p>Evidence of the following:</p> <ul style="list-style-type: none"> <li>• Written policies and procedures for ensuring an environment that provides privacy and dignity for participants, i.e. doors for exam rooms, privacy curtains, appropriate clothing and linen to cover participants during treatment, etc.;</li> <li>• The center must have lighting and sound levels in care areas, activity and dining rooms appropriate for individuals with vision, hearing, and cognitive impairments;</li> <li>• Proper ventilation;</li> <li>• Written policies and procedures for an effective pest control program to control household pests and rodents not limited to roaches, ants, flies, and mice;</li> <li>• Designated areas for smoking that are clearly marked and limited to participants and staff.</li> <li>• Posted signs that prohibit smoking while oxygen therapy is being administered and clearly designated universal oxygen</li> </ul>	<p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> NA</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p>	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	<p>signs.</p> <ul style="list-style-type: none"> <li>• Written policies and procedures to determine if or when participants may smoke without supervision.</li> <li>• Written policies and procedures on the proper storage, handling, and disposal of all chemicals, compounds and bio hazardous waste, including Material Safety Data Sheets for any chemical, cleaning and medical supplies;</li> <li>• Equipment stored in a manner to ensure participant's safety at all times.</li> </ul> <p>OTHER (SPECIFY)</p>	<input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> Other (Specify and Attach)	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
<p>I. C. The PACE center must include sufficient suitable space and equipment to provide primary medical care and suitable space for team meetings, treatment, therapeutic recreation, restorative therapies, socialization, personal care, and dining.</p>	<p>Evidence of Adequate Space For: (Adequate space would be determined by the provisions, if any, that are included in the PACE center Life Safety Code building occupancy license)</p> <ul style="list-style-type: none"> <li>• Team meetings</li> <li>• Medical treatment and other care</li> <li>• Therapeutic recreation</li> <li>• Restorative therapies</li> <li>• Socialization</li> <li>• Personal care</li> <li>• Dining</li> <li>• Evidence of sufficient and maintained equipment for safely transferring disabled participants on to exam tables and restorative therapy treatment equipment, such as tubs, beds, etc.</li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> MET</li> <li><input type="checkbox"/> NOT MET</li> <li><input type="checkbox"/> MET</li> <li><input type="checkbox"/> NOT MET</li> <li><input type="checkbox"/> MET</li> <li><input type="checkbox"/> NOT MET</li> <li><input type="checkbox"/> MET</li> <li><input type="checkbox"/> NOT MET</li> <li><input type="checkbox"/> MET</li> <li><input type="checkbox"/> NOT MET</li> <li><input type="checkbox"/> MET</li> <li><input type="checkbox"/> NOT MET</li> </ul>	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	OTHER (SPECIFY)	<input type="checkbox"/> Other (Specify and Attach)	
I. D. The PACE organization must establish, implement and maintain a written plan to ensure that all equipment is maintained in accordance with the	<ul style="list-style-type: none"> <li>• A written maintenance plan that identifies the individual responsible for the implementation and monitoring of the plan, what logs or records will be required, what equipment is included, and the maintenance schedules according to manufacturer's recommendations.</li> <li>• A written plan and monitoring program to check all contracts related to maintenance agreements.</li> </ul>	<input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET	

<b>PACE REGULATION REQUIREMENT</b>	<b>READINESS CRITERIA</b>	<b>CRITERIA MET</b>	<b>NOTES</b>
manufacturer's recommendations and keep all equipment (mechanical, electrical, and patient care) free of defect. This includes any equipment in the patient's home.	<ul style="list-style-type: none"> <li>• Written plans and procedures to report device related death and serious injuries to the FDA and/or the manufacturer of the equipment in accordance with the Safe Medical Devices Act of 1990.</li> <li>• Evidence of manufacturer's manuals for all equipment (mechanical, electrical, and patient care).</li> </ul> <p>OTHER (SPECIFY)</p>	<input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> Other (Specify and Attach)	
I.E. The PACE center must meet the occupancy provisions of the 2000 edition of the LSC for the type of setting in which it is located	<p><b>EVIDENCE OF COMPLIANCE WITH THE CURRENT EDITION OF THE LIFE SAFETY CODES.</b></p> <p>In addition have evidence of a:</p> <p>Fire Alarm System:</p> <ul style="list-style-type: none"> <li>• Initiation</li> <li>• Notification</li> <li>• Control               <ul style="list-style-type: none"> <li>• Air Condition Shutdown</li> <li>• Automatic release of fire doors held open by magnetic devices</li> </ul> </li> </ul> <p>Staff training and Drills            Fire evacuation Plans            Fire Procedures</p>	<input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	OTHER (SPECIFY)	<input type="checkbox"/> Other (Specify and Attach)	
<p>I.F. Establish, implement, and maintain documented procedures to manage medical and nonmedical emergencies and disasters that threaten the health and safety of participants, staff, or visitors.</p> <p>I.G. PACE organization must train all staff (employees and contractors) on the actions necessary to address different medical and nonmedical emergencies.</p>	<p>Evidence of:</p> <ul style="list-style-type: none"> <li>• Written plan and procedures to manage medical emergencies, including responding to DNRs, or any other Advance directives; choking; chest pain; seizures; stopped breathing or cessation of heart;</li> <li>• Written plan and procedures(s) for the periodic examination of all emergency drugs to confirm expiration date(s) and inventory control;</li> <li>• Written plans and procedures for staff training on and drills for the center’s emergency procedures, including the use of emergency drugs and emergency equipment;</li> <li>• At least one staff member during hours the center(s) have participant’s present will be trained and certified in Basic Life Support (CPR).</li> <li>• Verify that emergency drugs and emergency equipment is readily available, operating, and clean including: <ul style="list-style-type: none"> <li>○ PORTABLE OXYGEN</li> <li>○ AIRWAYS</li> <li>○ SUCTION EQUIPMENT</li> <li>○ PHARMACEUTICALS APPROPRIATE TO STABILIZE PARTICIPANTS.</li> </ul> </li> </ul>	<input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
<p>I.H. The PACE center must have emergency equipment, along with staff who know how to use the equipment at the center at all times and immediately available to adequately support participants until Emergency Medical Assistance responds to the center.</p>	<ul style="list-style-type: none"> <li>• Written plan and procedures to manage nonmedical emergencies and any natural disasters affecting the center’s geographic location, including:</li> <li>• Method of containment of fire;</li> <li>• Evacuation plans and routes;</li> <li>• Adequate emergency lighting at exits and corridors;</li> <li>• Plans for power outages, problems with water supply, and transfer of participants to other sites that meet their special needs;</li> <li>• Periodic drills;</li> <li>• Plan for assuring the health and safety of participants at home to ensure their continuing care needs will be met;</li> <li>• Facility structure and characteristics that will accommodate an expedient and safe evacuation of staff, participants, and visitors;</li> </ul>	<input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	OTHER (SPECIFY)	<input type="checkbox"/> Other (Specify and Attach)	
INFECTION CONTROL (§460.74)			
<p>II. At a minimum, the PACE center must have an infection control plan that includes:</p> <p>A. Procedures to identify, investigate, control, and prevent infections in every center and in each participant's place of residence;</p> <p>B. Procedures to record any incidents of infection;</p> <p>C. Procedures to</p>	<p>Written policies and procedures for the investigation, control, and prevention of infections including:</p> <ul style="list-style-type: none"> <li>• A written OSHA Exposure Control Plan which includes the Universal Precautions and Blood borne Pathogen exposure procedures for staff;</li> <li>• Vaccinating participants and staff against diseases of particular concern for the PACE participant and the center's geographic location, i.e. influenza and pneumonia (are required minimally);</li> <li>• Initial and ongoing health screening and vaccinations for staff and participants in accordance with OSHA regulations (staff) and CDC guidelines for tuberculosis, Hepatitis B and other communicable diseases.</li> <li>• Written plans and procedures for the investigation, evaluation, resolution, and reporting of all incidences of staff and participant infection.</li> </ul>	<p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET</p>	

<b>PACE REGULATION REQUIREMENT</b>	<b>READINESS CRITERIA</b>	<b>CRITERIA MET</b>	<b>NOTES</b>
<p>analyze the incidents of infection, to identify trends, and develop corrective actions related to the reduction of future incidents.</p>	<ul style="list-style-type: none"> <li>• Written plans and procedures for maintaining records of staff and participant infections to include post-exposure evaluation, training records, and participant and staff surveillance reports.</li> <li>• Written plans and procedures for reporting required communicable diseases to the appropriate state and local officials.</li> <li>• Plans and procedures for staff providing direct care to patients with infection(s);</li> <li>• Provision of adequate facilities and supplies necessary for infection control to include: <ul style="list-style-type: none"> <li>• Hand washing facilities and supplies;</li> <li>• Laundry facilities and supplies;</li> <li>• Isolation facilities and supplies</li> </ul> </li> </ul>	<input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET	

<b>PACE REGULATION REQUIREMENT</b>	<b>READINESS CRITERIA</b>	<b>CRITERIA MET</b>	<b>NOTES</b>
	<ul style="list-style-type: none"> <li>• Written plans and procedures for addressing how laundry will be handled. If the service is contracted out, written agreements to comply with the requirements.</li> <li>• Written plans and procedures for the ongoing monitoring of the contractual agreement provisions for laundry and waste disposal.</li> <li>• Written plans and procedures for the appropriate handling and disposal of all waste products including blood and urine specimens for outside lab tests and other bio hazardous wastes.</li> </ul> <p>OTHER (SPECIFY)</p>	<input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> NA  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> Other (Specify and Attach)	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
Transportation Services (§460.76)			
<p>III. The PACE organization should take appropriate steps to ensure that participants can be safely transported from their homes to the center and to appointments.</p> <p>A. Requirements for the organization's transportation program include:</p> <p>1. Maintenance of transportation vehicles according to the manufacturer's recommendations.</p> <p>2. Transportation vehicles</p>	<p>Evidence of appropriate state vehicle inspections.</p> <p>If commercial vehicles (greater than 12 seats, usually) are being used, a commercial license is required by all drivers.</p> <p>If the service is contracted out, written agreements to comply with the contract requirements under §460.70.</p> <p>Written plans and procedures for the ongoing monitoring of the contractual agreement provisions for transportation services.</p> <p>Evidence of the ability to provide adequate and safe transportation of center participants:</p> <ul style="list-style-type: none"> <li>• Sufficient staff</li> <li>• Written policies and procedures for the training and monitoring of drivers including:</li> </ul>	<p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> NA</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> NA</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p>	

<b>PACE REGULATION REQUIREMENT</b>	<b>READINESS CRITERIA</b>	<b>CRITERIA MET</b>	<b>NOTES</b>
<p>equipped to communicate with the PACE center.</p> <p>3. Training transportation personnel on the special needs of participants and appropriate emergency responses.</p> <p>4. As a part of the multi-disciplinary process, communicating relevant changes in the participant's care plans to transportation personnel.</p>	<ul style="list-style-type: none"> <li>• Proper transfer of nonambulatory and ambulatory participants;</li> <li>• Proper use of equipment needed to transfer and secure participants;</li> <li>• Emergency procedures during transfer, transport, and arrival of participants.</li> <li>• Ability for communication between the driver and center during transportation activities.</li> <li>• Evidence of written policies and procedures on the maintenance of vehicles utilized in the transport of participants.</li> <li>• Written plans and procedures for communicating between the multidisciplinary team and the transport staff the needs of the participants being transported.</li> <li>• Written plans and procedures for monitoring the performance of</li> </ul>	<input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	<p>all drivers.</p> <ul style="list-style-type: none"> <li>• Written procedures to check or audit for the following information on the drivers: <ul style="list-style-type: none"> <li>• Current driver's license</li> <li>• Record of any traffic violations or accidents that may constitute a potential hazard for the transport of participants.</li> </ul> </li> </ul> <p>OTHER (SPECIFY)</p>	<input type="checkbox"/> Other (Specify and Attach)	
Dietary Services (\$460.78)			
IV. PACE center is required to provide food that is nourishing, palatable, well-balanced, and meets acceptable	Evidence of certification or licensure from state or local health agencies for the preparation and/or serving of food (including the last Department of Health Inspection).	<input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> NA	



PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	<ul style="list-style-type: none"> <li>• Provisions for substitute foods or nutritional supplements;</li> <li>• Safe garbage storage and disposal;</li> <li>• Training of staff in safe food delivery; and</li> <li>• Written policies and procedures for emergency food supplies and emergency nutritional supplements.</li> </ul> <p>Written policies and procedures for dietitian, physician, and pharmacist involvement to determine the nutritional adequacy of menus and the caloric and nutritional needs for the participant population.</p> <p>OTHER: List outside vendors/contracts:</p>	<input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> Other (Specify and Attach)	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
Bill of Rights (§460.110)			
<p>V. The PACE organization must have written policies and implement procedures to ensure that the participant, his or her representative, and staff understand their rights.</p>	<p>Written policies and procedures governing the participant Bill of Rights including:</p> <ul style="list-style-type: none"> <li>• The parameters on the use of physical or chemical restraints;</li> <li>• The reporting of mental or physical abuse or neglect.</li> </ul> <p>Written policies and procedures for distributing the Bill of Rights to the participant and his or her representative upon enrollment.</p> <p>Written policies and procedures to ensure that the participant and his or her representative understand their rights.</p> <p>The participant Bill of Rights should be in English and any other principal language of the community and be displayed in an area frequented by the public. <i><u>Evidence of compliance with State requirement, if any, for specific criteria of the principle language</u></i></p> <p>The participant Bill of Rights should be in a large print for the elderly to read.</p>	<p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET</p>	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	<p>Written policies and procedures to respond to and Rectify a violation of a participant’s rights.</p> <p>OTHER (SPECIFY)</p>	<input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> OTHER (Specify and Attach)	
Personnel Qualifications (\$460.64)			
VI. The PACE center must have qualified staff to provide care to its frail elderly participants.	Signed contracts for all contractors and contracted personnel by the time the PACE center becomes operational.  Written position descriptions for all staff (employees and contractors).  Evidence (by the State completion of the assurance page, in the application, for this element) that the required members of the multidisciplinary team (primary care physician, registered nurse, social worker, recreational therapist or activities coordinator, PACE center manager, home care coordinator, and PACE center personal care attendants, drivers) are/will be employees or contractors of the PACE center.	<input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	<p>Evidence that appropriate professional licenses/certifications have been verified by primary source (licensing/certification board) and background checks have been done on all staff – employees and contractors (per state law requirements). If no direct participant care employees are yet hired then this review would entail the evidence of the procedures that will be completed to comply with this area.</p> <p>OTHER (SPECIFY)</p>	<input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> Other (Specify and Attach)	
<b>TRAINING AND COMPETENCY</b> (\$460.66 AND §460. 71)			
<b>VII.</b> <b>A.</b> The PACE organization must provide training to maintain and improve the skills and knowledge of each staff member with respect to the individual's	<p>Written individual competency and training programs for all team positions, specific to each position that includes at least the following:</p> <ul style="list-style-type: none"> <li>• Competency program to ensure that each staff member initially and ongoing demonstrates competency in the skills needed to provide appropriate, culturally competent care to participants. The competency program must include: <ul style="list-style-type: none"> <li>○ Initial hires and ongoing skills demonstration;</li> </ul> </li> </ul>	<input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET	

<p align="center"><b>PACE REGULATION REQUIREMENT</b></p>	<p align="center"><b>READINESS CRITERIA</b></p>	<p align="center"><b>CRITERIA MET</b></p>	<p align="center"><b>NOTES</b></p>
<p>specific duties that results in his or her continued ability to demonstrate the skills necessary for the performance of the position.</p> <p>B. The PACE organization must develop a training program for each personal care attendant to establish the individual's competency in furnishing personal care services and specialized skills associated with specific care needs of individual participants.</p>	<ul style="list-style-type: none"> <li>○ Skills demonstration method of evaluation based on standard protocols;</li> <li>○ Competent evaluator (including peer evaluator);</li> <li>○ Skills that reflect scope of practice and appropriate for the PACE center, home setting and level of care.</li> <li>● Training should be specific and within the scope of practice. To include at least the following: <ul style="list-style-type: none"> <li>○ Training and demonstrated competency on the transport of nonambulatory participants for drivers and any other applicable staff;</li> <li>○ Training and demonstrated competency on all emergency equipment and all other equipment necessary for the performance of his or her specific position;</li> <li>○ Training and demonstrated competency on center emergency procedures;</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> MET</li> <li><input type="checkbox"/> NOT MET</li> <li><input type="checkbox"/> MET</li> <li><input type="checkbox"/> NOT MET</li> <li><input type="checkbox"/> MET</li> <li><input type="checkbox"/> NOT MET</li> <li><input type="checkbox"/> MET</li> <li><input type="checkbox"/> NOT MET</li> <li><input type="checkbox"/> MET</li> <li><input type="checkbox"/> NOT MET</li> <li><input type="checkbox"/> MET</li> <li><input type="checkbox"/> NOT MET</li> </ul>	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	<ul style="list-style-type: none"> <li>○ Training and demonstrated competency on restraint use;</li>   <li>○ Training and demonstrated competency on participant rights, including dignity and privacy, to all participants;</li>   <li>○ Training and demonstrated competency in response to participant grievances or center quality improvement activities; and</li>   <li>○ Training and demonstrated competency in therapeutic communication specific to the PACE setting and population.</li>   <li>● Written training manual for personal care attendants to ensure that they exhibit competency in basic skills for providing personal care, including: <ul style="list-style-type: none"> <li>○ How to maintain a clean, safe and healthy environment;</li>   <li>○ Appropriate and safe techniques in personal hygiene and grooming;</li>   <li>○ Safe transfer techniques and ambulation;</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> MET</li> <li><input type="checkbox"/> NOT MET</li>   <li><input type="checkbox"/> MET</li> <li><input type="checkbox"/> NOT MET</li>   <li><input type="checkbox"/> MET</li> <li><input type="checkbox"/> NOT MET</li>   <li><input type="checkbox"/> MET</li> <li><input type="checkbox"/> NOT MET</li>   <li><input type="checkbox"/> MET</li> <li><input type="checkbox"/> NOT MET</li>   <li><input type="checkbox"/> MET</li> <li><input type="checkbox"/> NOT MET</li>   <li><input type="checkbox"/> MET</li> <li><input type="checkbox"/> NOT MET</li> </ul>	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	<ul style="list-style-type: none"> <li>○ Observation, reporting, and documentation of patient status and the care or service furnished.</li> <li>○ Training in therapeutic communication specific to the PACE setting and population; and</li> <li>○ Other elements consistent with their assigned duties.</li> </ul> <p>OTHER (SPECIFY)</p>	<input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> MET <input type="checkbox"/> NOT MET  <input type="checkbox"/> Other (Specify and Attach)	
GENERAL PROVISIONS			
VIII. General provisions	<p>Evidence of all current licensure required in the State:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> ADHC</li> <li><input type="checkbox"/> HH</li> <li><input type="checkbox"/> Clinic</li> <li><input type="checkbox"/> HMO</li> <li><input type="checkbox"/> Ambulatory Care Center</li> <li><input type="checkbox"/> Other - specify</li> </ul> <p>Written plans and procedures regarding the safeguarding of participant data and records according to HIPAA compliance for security (electronic and paper).</p>	<input type="checkbox"/> MET <input type="checkbox"/> NOT MET          <input type="checkbox"/> MET <input type="checkbox"/> NOT MET	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	<p>Written plans and procedures regarding the confidentiality and retention of participant health information.</p> <p>Written plan and procedures for all participant reassessments which include periodic reassessments and reassessments at the participant or caregiver's request.</p> <p>Verify the PACE organization's actual service area.</p> <p>Verify the process the PACE organization has in place to ensure participant access to care 24 hours a day, 7 days a week.</p> <p>Verify that all required services will be provided by the PACE organization.</p> <p>Evidence of a health information system to collect, analyze, and report participant data.</p> <p>Identify any additional sites:</p> <p>OTHER (SPECIFY)</p>	<p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> NA</p> <p><input type="checkbox"/> Other (Specify and Attach)</p>	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
General Safety Requirements			
IX. Overall PACE center safety requirements	<p>Evidence of state pharmacy licensure.</p> <p>Written plans and procedures for narcotic inventory control and disposal.</p> <p>All Medications are locked in a cabinet, room or cart.</p> <p>Written plans and procedures for refrigerator temperature logs used for medication and food storage.</p> <p>Written plans and procedures for oxygen storage that is in compliance with fire safety and FDA laws.</p> <p>Evidence of CLIA certification if the PACE center is performing waived lab services on site or in the home, e.g. glucose meter testing, urine testing, fecal occult testing, blood testing, cholesterol screening, or hemoglobin or hematocrit testing.</p>	<input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> NA <input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> MET <input type="checkbox"/> NOT MET	

<b>PACE REGULATION REQUIREMENT</b>	<b>READINESS CRITERIA</b>	<b>CRITERIA MET</b>	<b>NOTES</b>
	OTHER (SPECIFY)	<input type="checkbox"/> Other (Specify and Attach)	

This version completed October 28, 2003