

PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY

For all new applicants and existing PACE Organizations seeking to expand a service area

**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)**

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1 GENERAL INFORMATION

1.1 Overview

The Programs of All-Inclusive Care for the Elderly (PACE) is a pre-paid, capitated plan that provides comprehensive health care services to frail, older adults in the community, who are eligible for nursing home care according to State standards. PACE programs must provide all Medicare and Medicaid covered services; financing of this model is accomplished through prospective capitation of both Medicare and Medicaid payments.

CMS regulations at 42 CFR § 460.98(b) (2) require a PACE Organization (PO) to provide PACE services in at least the PACE center, the home, and inpatient facilities. The PACE center is the focal point for the delivery of PACE services; the Center is where the interdisciplinary team (IDT) is located, services are provided, and socialization occurs with staff that is consistent and familiar to participants. 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 furnished in accordance with the PACE participant's needs, as determined necessary by the IDT. To provide PACE participants with flexibility regarding access to quality care, CMS has allowed POs to offer some services in other settings which are referred to as an ACS. An ACS can be any physical location in the PO's CMS approved existing service area other than the participant's home, an inpatient facility, or PACE center.

Section 4801 of the Balanced Budget Act of 1997 (BBA)(Pub. L. 105-33) 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. The regulations implementing these PACE statutory requirements are set forth in 42 CFR Part 460.

The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, (BIPA) amended the PACE statute to provide authority for CMS to modify or waive PACE regulatory provisions. CMS-1201-IFC, Programs of All-inclusive Care for the Elderly (PACE); Program Revisions, published October 1, 2002, 67 FR 61496, established a process through which existing and prospective POs may request a waiver of Medicare and Medicaid regulatory requirements. 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 reimbursed 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.

In 2006, CMS 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).

1.2 Technical Support

CMS conducts special training sessions for all new and existing 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 are available to provide Health Plan Management System (see Section 1.3, below) technical support to all applicants and answer questions 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.

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, the Part D bid submission process, and for reporting and oversight activities.
- B. Applicants are required to enter contact and other information 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 the application is approved and CMS executes a 3-way program agreement with the applicant entity and the applicable State, this contact information will also be used for frequent communications during the operational period of the PACE program. Therefore, it is important that this information be accurate at all times.
- C. HPMS is also the vehicle used to disseminate CMS guidance to POs. This information is then incorporated into the appropriate manuals. It is imperative for POs to independently check HPMS memos and follow the guidance as indicated in the memos.

1.4 Submitting Notice of Intent to Apply (NOIA)

Organizations interested in becoming a new PO or expanding the service area of an existing product must complete a nonbinding NOIA. CMS will not accept applications from organizations that fail to submit a timely NOIA.

For new applicants, 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 applicant’s 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 CFR 42 CFR §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.

2 INSTRUCTIONS

2.1 Overview

Applicants must complete the PACE initial and service area expansion application using HPMS as instructed. 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” or “N/A” 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.

Throughout this application, applicants are asked to provide various documents and/or tables in HPMS. All required documents to be submitted are specified at the end of each attestation section; a chart of all required attestations and uploads is also included in Section 2.3.

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 PO for the first time.

Service Area Expansion Applications are for:

- Existing PACE organizations who are seeking to expand the service area of an existing contract number.

2.3 Chart of Required Attestations and Uploads

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

Chart 1 - Required Attestations and Uploads

Attestation Topic	Section #	Initial	SAE	Upload Required (Initial)	Upload Required (SAE)
Service Area	3.1	X	X	X	X
Legal Entity and Organizational Structure	3.2	X		X	
Governing Body	3.3	X		X	
Fiscal Soundness	3.4	X	X	X	X
Marketing	3.5	X	X	X	X
Explanation of Rights	3.6	X		X	
Grievance	3.7	X		X	
Appeals	3.8	X		X	
Enrollment	3.9	X		X	
Disenrollment	3.10	X		X	

Personnel Compliance	3.11	X			
Program Integrity	3.12	X			
Contracted Services	3.13	X	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	X		
Dietary Services	3.24	X			
Termination	3.25	X		X	
Maintenance of Records & Reporting Data	3.26	X			
Medical Records	3.27	X			
Quality Assessment Performance Improvement Program (QAPI)	3.28	X		X	
State Attestations	3.29	X		X	X
Waivers	3.30	X		X (as applicable)	
Application Attestations	3.31	X	X	X	X
State Readiness Review	3.32	X	X (as applicable)	X	X (as applicable)

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 is to be completed by those newly forming POs that intend to provide the Part D benefit to eligible participants. Applicants must use the current Medicare Part D Application for new POs that can be accessed via the link below. CMS will not accept or review in any way those submissions using prior versions of the application.

The Medicare Part D Application for new POs can be found at:
http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ApplicationGuidance.html.

The Part D application must be submitted simultaneously with this PACE application

and both will be reviewed within the same timeframes.

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:

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: SERVICE AREA	YES	NO
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).		

B. In HPMS, on the Contract Management/Contract Service Area/Service Area Data page, enter the state and county information for the area the Applicant proposes to serve.

C. 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.

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:

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: LEGAL ENTITY AND ORGANIZATIONAL STRUCTURE	YES	NO	N/A
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 PO (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. For any change in organizational structure that includes a Change of Ownership, the applicant agrees to abide by the general provisions described in the MA regulations at 42 CFR 422.550.			
8. Applicant ensures that they are organized to operate within the state consistent with all applicable state laws.			
9. If planning to do business as (d.b.a.) under a name that is different from the name 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 PO, 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 PO operations and participant concerns consistent with the requirements of 42 CFR §460.62.

A. In HPMS, complete the table below:

RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: GOVERNING BODY	YES	NO
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"> • Governance and operation; • Development of policies consistent with its mission; • Management and provision of all services, including the management of subcontractors; • Personnel policies (that address adequate notice of termination by employees or contractors with direct participant care responsibilities); • Fiscal operations; • Development of policies on participant health and safety; and • QAPI program. (see 42 CFR §460.62(a)(1-7))		
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 governing body members and their titles. Indicate which members are PACE participant representative(s). 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 §460.60(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:

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: FISCAL SOUNDNESS	YES	NO	N/A
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"> • Total assets greater than total unsecured liabilities; • Sufficient cash flow and adequate liquidity to meet obligations as they become due; and • A net operating surplus or a financial plan for maintaining solvency that is satisfactory to CMS and the State administering agency (SAA). 			
2. Applicant agrees to provide CMS a copy of the executed subordinated debt agreement for each financial reporting period.			
3. Applicant agrees to upload a documented plan in the event of insolvency as specified in 42 CFR §460.80(b).			
4. Applicant agrees to provide CMS and the SAA accurate financial reports as specified in 42 CFR §460.204.			
5. 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.			
6. Applicant agrees to provide any reserve requirements and other financial requirements set by the State in which the applicant proposes to operate its PACE program, and any supporting documentation necessary to demonstrate how the applicant meets these requirements.			

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

Note: If the PACE legal entity (applicant) is a line of business of the parent organization, and audited annual financial statements are not available at the PACE legal entity level, the applicant may provide audited statements relating to the parent organization. The applicant may also upload independently audited financial statements of guarantors and lenders (e.g. organizations providing loans, letters of credit or other similar financing arrangements, excluding banks), if

audited financial statements are not available for either the legal entity or the parent organization.

Audits provided in the Documents section of the application, must include:

- Opinion of a certified public accountant;
 - Statement of revenues and expenses;
 - Balance sheet;
 - Statement of cash flows;
 - Explanatory notes; and
 - Statements of changes in net worth.
- C. In the Documents Section, upload the most recent year-to-date unaudited financial statements of the PACE applicant legal entity, or if unavailable, for the parent organization, guarantors or lenders.
- D. 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
 - Projections in gross dollars which 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;
 - 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 POs.
- E. In the Documents Section, upload the subordinated debt attestation form (if applicable).

Note: Subordinated debt is defined as an unsecured debt whose repayment to its parent organization ranks after all other debts have been paid when the subsidiary

files for bankruptcy. If subordinated debt is identified by the PACE organization (legal entity), it should be included in the total PACE liabilities and the amount of subordinated debt must be clearly identified on the balance sheet of the financial statements and financial projections (if applicable). Please submit a detailed description, including the name and nature of the subordinated debt amount.

- F. In the Documents Section, upload your Insolvency Plan.
- G. In the Documents Section, upload documents that demonstrate the applicant 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.) (42 CFR §460.80)
- H. 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 (if applicable).

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:

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: MARKETING	YES	NO
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"> • Description or list of benefits and services; • Description of premiums or other payment responsibilities; and • Other information necessary for prospective participants to make an informed decision about enrollment. 		

<p>2. Applicant agrees that the following information on restriction in services is included in their marketing materials:</p> <ul style="list-style-type: none"> • Participant must receive all needed health care, including primary care and specialist physician services (other than emergency services), from the PO or from an entity authorized by the PO; and • Participants may be fully and personally liable for the costs of unauthorized or out-of-network services. 		
<p>3. Applicant agrees that the marketing material is free of inaccuracies, misleading information, or misrepresentations.</p>		
<p>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.</p>		
<p>5. Applicant agrees to obtain CMS Regional Office approval of all marketing information before distribution.</p>		
<p>6. Applicant agrees that its employees or agents will not use the following prohibited marketing practices in accordance with 42 CFR 460.82(e)(1-5):</p> <ul style="list-style-type: none"> • Discrimination of any kind, except that marketing may be directed to individuals eligible for PACE by reason of their age; • Activities that could mislead or confuse potential participants or misrepresent the PO, CMS, or the SAA; • Gifts or payment to induce enrollment; • Contracting outreach efforts to individuals or organizations whose sole responsibility involves direct contact with the elderly to solicit enrollment; and • Unsolicited door-to-door marketing. 		
<p>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).</p>		
<p>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.</p>		

NOTE: Marketing materials are captured separately, via the HPMS PACE marketing module. Applicants should upload marketing materials in the HPMS marketing module for CMS/State review and approval. All marketing materials must be approved before an approved PO can begin PACE program operations.

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:

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: EXPLANATION OF RIGHTS	YES	NO
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"> • Write the participant's rights in English and in any other principal languages of the community; and • Display the participant's rights in a prominent place in the PACE center as specified in 42 CFR §460.116(c)(1)(2). 		
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:

YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: GRIEVANCES	YES	NO
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"> • How a participant files a grievance; • Documentation of a grievance; • Response to and resolution to a grievance in a timely manner; and <ul style="list-style-type: none"> • Maintenance of confidentiality of the grievance (see 42 CFR §460.120(a)). 		
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:

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: APPEALS	YES	NO
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): <ul style="list-style-type: none"> • Written denials of coverage or payment are prepared and processed timely; • How a participant files an appeal; • Documentation of participant's appeal; • 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; • 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 • Confidentiality of a participant's appeal is maintained. 		
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.		
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>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"> • The PO is proposing to terminate or reduce services currently being furnished to the participant; and • 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. 		
<p>5. Applicant agrees to furnish all other required services to the participant as specified in 42 CFR §460.122(e)(2).</p>		
<p>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).</p>		
<p>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).</p>		
<p>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).</p>		
<p>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).</p>		
<p>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).</p>		
<p>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):</p> <ul style="list-style-type: none"> • The participant requests the extension; and • The organization justifies to the SAA the need for additional information and how the delay is in the interest of the participant. 		
<p>12. Applicant agrees to do the following as specified in 42 CFR §460.124:</p> <ul style="list-style-type: none"> • Inform a participant in writing of his or her additional appeal rights under Medicare or Medicaid managed care, or both; and • Assist the participant in choosing which external appeal avenue to pursue, and forward the appeal to the appropriate external entity. 		

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:

RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: ENROLLMENT	YES	NO
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"> • Is 55 years of age or older; • Is determined by the SAA to need the nursing facility services level of care for coverage under the State Medicaid plan; • Resides in the PO service area; • Meets any additional program specific eligibility conditions imposed under the PACE program agreement; and • Able to live in a community setting without jeopardizing his or her health or safety as determined by criteria specified in the program agreement. • 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. 		
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"> • Exhibits and explains each element of the enrollment agreement; • Informs participant that PACE is the sole service provider; • Informs participant that PACE guarantees access to all necessary services, but not access to specific providers; • Provides a list of employed and contracted staff who deliver PACE services; • Discloses required monthly premium if applicable; • Discloses Medicaid spend-down obligations if applicable; • Discloses post-eligibility treatment of income if applicable; • Requires a signed release form for PACE to obtain medical, financial, and Medicare and Medicaid eligibility information; • Requires assessment by the SAA to determine eligibility for nursing facility services (NF) level of care coverage under the State Medicaid Plan; and • 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. <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"> • Notify the individual in writing of the reason for the denial; • Refer the individual to alternative services, as appropriate; • Maintain supporting documentation of the written notification; and • Notify CMS and SAA and make documentation available for review. 		
<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"> • A copy of the enrollment agreement; • A PACE membership card; • Emergency information to be posted in the participant's residence explaining PACE membership and how to access emergency services; and • PACE program stickers for Medicare and Medicaid cards that include the PACE phone number. 		

<p>7. Applicant agrees to submit participant information to CMS and SAA in accordance with established procedures as specified in 42 CFR §460.156(b).</p>		
<p>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):</p> <ul style="list-style-type: none"> • Give an updated copy to the participant; and • Explain the changes to the participant, caregiver, or representative in a way they understand. 		
<p>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 PO receives the signed enrollment agreement as specified in 42 CFR §460.158.</p>		
<p>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):</p> <ul style="list-style-type: none"> • The participant voluntarily disenrolls; or • The participant is involuntarily disenrolled in accordance with PACE regulations. 		
<p>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).</p>		
<p>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 revaluation 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).</p>		
<p>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):</p> <ul style="list-style-type: none"> • 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. 		

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.

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:

RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: DISENROLLMENT	YES	NO
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"> • Have a policy and procedure in place to document the reasons for all voluntary and involuntary disenrollments; • Make documentation available for review by CMS and the SAA; and • Use the internal QAPI program to review documentation on voluntary disenrollment. 		
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"> • Participant fails to pay, or to make satisfactory arrangements to pay, any premium due the PO after a 30-day grace period; • Participant moves out of the PACE program service area or is out of the service area for more than 30 consecutive days, unless the PO agrees to a longer absence due to extenuating circumstances; • Participant is determined to no longer meet the State Medicaid nursing facility level of care requirements and is no longer deemed eligible; • PACE program agreement with CMS and the SAA is not renewed or is terminated; • PO is unable to offer health care services due to the loss of State licenses or contracts with outside providers; • Participant engages in disruptive or threatening behavior by exhibiting behavior that jeopardizes his or her health or safety, or the safety of others; and • Participant with decision-making capacity refuses to comply with the care plan or terms of the enrollment agreement. 		
<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"> • Reason for the proposed involuntary disenrollment; and • Efforts to remedy the situation. 		
<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"> • Use the most expedient process allowed under Medicare and Medicaid procedures and set forth in the PACE program agreement; • Coordinate the disenrollment date between Medicare and Medicaid (for dual eligible participants); • Give reasonable advance notice to the participant; and • Continue to deliver PACE services to the participant until the date enrollment is terminated. 		
<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"> • Make appropriate referrals and transmit copies of medical records to new providers in a timely manner; and • Work with CMS and SAA to reinstate the participant in other Medicare and Medicaid programs for which the participant is eligible. 		
<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 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:

RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: PERSONNEL COMPLIANCE	YES	NO
<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"> • Are legally authorized (e.g., currently licensed, registered, or certified if applicable) to practice in the state in which they perform the function or action as evidenced by primary verification of licenses or certifications; • Act within the scope of their authority to practice; • Have one year of experience with a frail or elderly population; • Meet a standardized set of competencies for the specific position description established by the applicant and approved by CMS prior to working independently; and • Be medically cleared for communicable diseases and have all immunizations up-to-date prior to engaging in direct participant contact. <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 individual’s 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"> • Comply with State or Federal requirements for direct patient care staff in their respective settings. • Comply with requirements of 42 CFR §460.68(a), regarding persons with criminal convictions. • Have verified current certifications or licenses for their respective positions. • Are free of communicable diseases and are up to date with immunizations before performing direct patient care, • Have been oriented to the PACE program, and • Agree to abide by the philosophy, practices, and protocols of the PO. 		

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:

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: PROGRAM INTEGRITY	YES	NO
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 individual's 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:

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: CONTRACTED SERVICES	YES	NO
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 PO except for emergency services as specified in 42 CFR §460.70(a), and 42 CFR §460.100.		

<p>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:</p> <ul style="list-style-type: none"> • An institutional contractor, such as a hospital or skilled nursing facility, must meet Medicare or Medicaid participation requirements; • A practitioner or supplier must meet Medicare or Medicaid requirements applicable to the services delivered; • Contractors must comply with the PACE requirements for service delivery, participant rights, and participation in QAPI activities; and • Contractors must be accessible to participants and located either within or near the PO's service area. 		
<p>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).</p>		
<p>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).</p>		
<p>5. Applicant agrees to develop an oversight process that the PO will use to ensure that contracts and contractors meet PACE program and Federal requirements, inclusive of being HIPAA compliant.</p>		
<p>6. Applicant agrees that each contract contains the requirements as specified in 42 CFR §460.70(d)(1-5).</p>		
<p>7. Applicant acknowledges it cannot contract with another entity to furnish PACE Center Services unless 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.</p>		

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 §460.92, and §460.96.

A. In HPMS, complete the table below:

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: REQUIRED SERVICES	YES	NO
<p>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:</p> <ul style="list-style-type: none"> • All Medicare-covered items and services; • All Medicaid-covered items and services as specified in the State's approved Medicaid plan; and • Other services that the IDT determines are necessary to improve and maintain the participant's overall health status. 		
<p>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:</p> <ul style="list-style-type: none"> • Services not authorized by the IDT, even if a required service, unless it is an emergency service; • Inpatient private room and/or private duty nursing (unless medically necessary) and non-medical items for personal convenience (unless authorized by IDT); • 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; • Experimental medical, surgical, or other health procedures; and • Services delivered outside the United States (except for those services furnished in accordance with regulatory requirements and as permitted under the State's approved Medicaid Plan). 		

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:

RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: SERVICE DELIVERY	YES	NO
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"> • Including comprehensive medical, health, and social services that integrate acute and long-term care; and • 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. 		
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"> • Primary care including physician and nursing services; • Social services; • Restorative therapies including physical therapy and occupational therapy; • Personal care and supportive services; • Nutritional counseling; • Recreational therapy; • Meals; and • Care management by an interdisciplinary care team. 		

<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"> • Have sufficient capacity to allow routine attendance by participants; • Is accessible and has adequate services to meet the needs of its participants; • Offers the full range of services with sufficient staff to meet the needs of participants at each center if the PO operates more than one center; and • Have participants attend the center as frequently as the IDT determines is necessary based upon the preferences and needs of each participant. 		
<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"> • Manages the participant's medical situations; and • Oversees the participant's use and provision of care by medical specialists and inpatient facilities. 		

3.16 Infection Control

The purpose of this section is to ensure that all PACE applicants 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:

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: INFECTION CONTROL	YES	NO
<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: http://www.cdc.gov</p>		

<p>3. Applicant agrees to establish, implement and maintain an Infection Control Plan that meets the following requirements: (1) Ensures a safe and sanitary environment. (2) Prevents and controls the transmission of disease and infection.</p>		
<p>4. Applicant assures that its infection control plan includes, but is not limited to, the following: (1) Procedures to identify, investigate, control, and prevent infections in every PACE center and in each participant's place of residence. (2) Procedures to record any incidents of infection. (3) Procedures to analyze the incidents of infection to identify trends and develop corrective actions related to the reduction of future incidents.</p>		

3.17 Interdisciplinary Team

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

A. In HPMS, complete the table below:

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: INTERDISCIPLINARY TEAM	YES	NO
<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"> • Managing participant medical situations; and • Overseeing the participant use of medical specialists and inpatient care. 		
<p>4. Applicant ensures that the IDT does the following as specified in 42 CFR §460.102(d)(1), §460.102(d)(2), and §460.102(d)(3):</p> <ul style="list-style-type: none"> • Completes initial assessments, periodic reassessments, and plans of care; • Coordinates twenty-four hour care delivery; • Communicates regularly about, and remains alert to, the medical, functional, and psychosocial condition of each participant; • Documents changes of participant's condition in the medical record consistent with documentation policies established by the medical director; and • Serves primarily PACE participants. 		
<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:

RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: PARTICIPANT ASSESSMENT	YES	NO
1. Applicant ensures that participant assessments are comprehensive, in person, and include, at a minimum (42 CFR §460.104(4)): <ul style="list-style-type: none"> • Physical and cognitive function and ability; • Medication use (prescription, over the counter and alternative medications); • Participant and caregiver preferences for care; • Socialization and availability of family support; • Current health status and treatment needs; • Nutritional status; • Home environment including home access and egress; • Participant behavior; • Psychosocial status; • Medical and dental status; and • Participant language. 		
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): <ul style="list-style-type: none"> • Primary care physician; • Registered nurse; • Master's level social worker; • Physical therapist; • Occupational therapist; • Recreation therapist or activity coordinator; • Dietitian; • Home care coordinator; and • Other healthcare professionals as determined by the IDT. (See 42 CFR §460.104(2).)		

<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"> • Primary care physician; • Registered nurse; • Master's level social worker; • Recreational therapist or activity coordinator; and • Other healthcare professionals as determined by the IDT. 		
<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"> • Physical therapist; • Occupational therapist; • Dietitian; • Home care coordinator; and • Other healthcare professionals as determined by the IDT. 		
<p>6. Applicant ensures that IDT members conducting reassessments promptly complete the following:</p> <ul style="list-style-type: none"> • Reevaluate the care plan and discuss changes with the IDT and participant/caregiver; • Revise the plan of care and update measurable goals based on IDT and participant approval; • Deliver services identified in the revised care plan; and • Document assessments and any revisions to the plan of care in the participant medical record. 		
<p>7. Applicant ensures that the IDT conducts unscheduled reassessments when there are (42 CFR §460.104(d)):</p> <ul style="list-style-type: none"> • Changes in participant health or status or psychosocial status; <p>or</p> <ul style="list-style-type: none"> • Requests by participants/caregivers for reassessment. 		
<p>8. Applicant ensures that unscheduled reassessments are conducted face-to-face by the applicable IDT member.</p>		
<p>9. Applicant ensures that there are explicit procedures for performance of unscheduled reassessments requested by the participant/caregiver (42 CFR §460.104(d)(2)).</p>		

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:

RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: PLAN OF CARE	YES	NO
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 o Intervention; o Measurable outcomes to be achieved; o Implementation frequency intervention; o Staff responsible; and o Outcome met/not met.		
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.		
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.		
7. Applicant ensures that the IDT provides documentation in the medical record for the following: • Original plan of care; • Ongoing changes to the plan of care; • Participant/caregiver preferences and concerns; and • IDT discussion that demonstrates collaborative participation in developing and updating the single comprehensive plan of care.		

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:

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: RESTRAINTS	YES	NO
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.		
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.		

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:

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: PHYSICAL ENVIRONMENT	YES	NO
1. Applicant ensures a PACE center which: <ul style="list-style-type: none"> • Is designed, constructed, equipped, and maintained to provide physical safety for participants, personnel, and visitors; and • Provides a safe, sanitary, functional, accessible, and comfortable environment for the delivery of services and preservation of participant dignity and privacy. 		
2. Applicant ensures that suitable space and equipment exist to provide the following: <ul style="list-style-type: none"> • Primary medical care and treatment; • Therapeutic recreation; • Team meetings; • Restorative therapies; • Personal care; • Socialization activities; and • Dining services. 		
3. Applicant ensures that all equipment is maintained according to manufacturer's recommendations.		
4. Applicant ensures the PACE center meets the occupancy provisions of the current edition of the National Fire Protection Association's Life Safety Code that apply to the type of setting in which the center is located. Note: Exceptions are specified in 42 CFR §460.72(b).		

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:

RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: EMERGENCY AND DISASTER PREPAREDNESS	YES	NO
1. Applicant ensures availability of emergency equipment at each center as specified in 42 CFR §460.72(c)(4) which includes the following: <ul style="list-style-type: none"> • Portable oxygen; • Airways; • Suction; and • Emergency drugs. 		
2. Applicant ensures that staff who know how to use the emergency equipment are on the premises of every center at all times and are immediately available to use the emergency equipment.		
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).		
4. Applicant ensures that the emergency plan holds harmless CMS, the State, and the PACE participant if the PO does not pay for emergency services as specified in 42 CFR §460.100(a).		
5. Applicant agrees to provide for emergency services, both inpatient and outpatient settings, by a qualified emergency services provider, other than the PO or one of its contract providers, either in or out of the PO's service area, in order to evaluate or stabilize an emergency medical condition as specified in 42 CFR § 460.100(b).		
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 PO, the PO cannot be contacted, or the PO did not respond to a request for approval within 1 hour after being contacted as specified in 42 CFR §460.100(2)(i)(ii).		
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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:

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: TRANSPORTATION SERVICES	YES	NO
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, PO 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).		

7. Applicant agrees that the transportation system has been modified to accommodate the proposed service area/site expansion.		
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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:

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: DIETARY SERVICES	YES	NO
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. Applicant agrees to provide meals that meet the following requirements consistent with 42 CFR §460.78 (a): 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 (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"> • Tube feedings; • Total parenteral nutrition; and • Peripheral parenteral nutrition. (42 CFR §460.78(a)(3)).		

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:

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

B. In the Documents Section, upload your termination plan.

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

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:

RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: MAINTENANCE OF RECORDS & REPORTING DATA	YES	NO
1. Applicant ensures data collection, record maintenance, and report submission as required by CMS and the State. Note: Reports include those necessary for CMS and the State to monitor the operation, cost, quality, effectiveness of the program, and establish payment rates.		
2. Applicant ensures CMS and SAA access to data and records including, but not limited to: <ul style="list-style-type: none"> • Participant health outcome data; • Financial books and records; • Medical records; and • Personnel records. 		
3. Applicant ensures policies and procedures to safeguard data, books and records against the following: <ul style="list-style-type: none"> • Loss; • Destruction; • Unauthorized use; and • Inappropriate alteration. 		
4. Applicant ensures confidentiality of health information through policies and procedures that do the following: <ul style="list-style-type: none"> • Safeguard privacy and confidentiality of participant health information, including mental health information, per HIPAA and other Federal and State laws; • Maintain complete records in an accurate and timely manner; and • Provide participants timely access to review and copy their own medical records as well as request amendments to the record. 		

5. Applicant ensures retention of records for the longest of the following periods: <ul style="list-style-type: none"> • Time specified in State law; • Six years from the last entry date in the record or for medical records of disenrolled participants, 6 years after the date of disenrollment; or • Completion of litigation or associated resolution of claims, financial management review or audit findings. 		
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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:

RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: MEDICAL RECORDS	YES	NO
1. Applicant agrees to maintain a single, comprehensive medical record for each participant.		
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: <ul style="list-style-type: none"> • Complete regardless of format (electronic or print); • Accurately documented; • Readily accessible to authorized personnel; • Systematically organized to facilitate review; • Available to employed or contracted staff; and • Maintained and housed at the PACE center where the participant receives services. 		
3. Applicant agrees to promptly transfer copies of pertinent medical record information to all providers delivering direct care in other healthcare settings per HIPAA.		

4. Applicant's medical records are appropriately authenticated by ensuring the following: <ul style="list-style-type: none"> • All entries must be legible, clear, complete, and appropriately authenticated and dated; and • Authentication must include signatures or a secured computer entry by a unique identifier of the primary author who has reviewed and approved the entry. 		
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3.28 Quality Assessment Performance Improvement Program (QAPI)

The purpose of this section is to ensure that all PACE applicants take appropriate actions to improve performance, including the establishment and operation of a QAPI in accordance with 42 CFR §460, Subpart H, §460.200, and §460.202.

A. In HPMS, complete the table below:

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: MEDICAL RECORDS	YES	NO
1. Applicant agrees to do the following as specified in 42 CFR §460.130: <ul style="list-style-type: none"> • Develop, implement, maintain and evaluate a QAPI program; • Reflect the full range of services furnished by the PO; and • Take action resulting in improvements in its performance in all types of care. 		
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-by doing the following: <ul style="list-style-type: none"> • Using a set of outcome measures to identify areas of good or problematic performance; • Taking actions targeted at maintaining or improving care based on outcome measures; • Incorporating improvements into standard practice to sustain performance; • Prioritizing performance improvement activities based on clinical outcomes, prevalence of the problem in the PACE population, and severity of the problem; and • Immediately correcting an identified problem that directly or potentially threatens the health or safety of participants. 		

<p>3. Applicant agrees that the designated QAPI coordinator will do the following as specified in 42 CFR §460.136:</p> <ul style="list-style-type: none"> • Coordinate and oversee implementation of the QAPI activities; and • Encourage PACE participants and caregivers to participate in QAPI activities, including providing information about their satisfaction with services. 		
<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.</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:</p> <ul style="list-style-type: none"> • Evaluate outcome data measuring quality performance; • Address the implementation of the QAPI plan and the results from quality improvement activities; and • Provide input related to ethical decision-making on issues such as end-of-life, participant self-determination, and other participant health rights and concerns. 		
<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>		
<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.</p>		
<p>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.</p>		
<p>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.</p>		
<p>10. Applicant ensures a written QAPI plan as specified in 42 CFR §460.132.</p>		

B. In the Documents Section, upload a copy of the HPMS data monitoring elements as specified in 42 CFR §460.202.

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 Attestation

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)).

A. In HPMS, complete the table below:

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: STATE ATTESTATIONS	YES	NO
1. Applicant has assurance from the SAA of the State in which the program is located indicating that the State considers the entity to be qualified to be a PO and is willing to enter into a PACE program agreement with the entity.		

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 Documents 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 Documents 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 applicants are permitted to submit waiver requests consistent with 42 CFR §460.26 and 42 CFR §460.28.

A. In HPMS, complete the table below:

RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: WAIVERS	YES	NO	N/A
1. 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.			
2. Applicant ensures that specific modifications or waivers of certain regulatory provisions as part of this application have been submitted to the SAA for review, as specified in 42 CFR 460.26(a)(2).			

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

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

A. Please upload your application attestation document.

3.32 State Readiness Review

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

A. 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. /Governing Body contact person:

Telephone Number:

3. Governing Body members/Board of Directors:

4.2 Subordinated Debt

If the applicant has a subordinated debt arrangement, the applicant must complete the “PACE Organization Attestation of Subordinated Debt Arrangement” form located at <https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/FSRR.html>. This completed form may be uploaded as part of the fiscal soundness part of the application (see section 3.4).

4.3 State Assurances 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 and operate in the proposed geographic service area.

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. (42 CFR §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. (42 CFR §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 required under the State Medicaid plan for coverage of nursing facility services. (42 CFR §460.160(b))

State agrees to establish a process that may permanently 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 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 to 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 determine in a timely manner that the applicant has adequately documented acceptable grounds for disenrollment. (42 CFR §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. (42 CFR §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. (42 CFR §460.168)

State agrees to make a prospective monthly payment to the applicant of a capitation amount for each participant. (42 CFR §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. (42 CFR §460.190 and 42 CFR §460.192)

State agrees that it will ensure that the Medicare benefit requirements are protected for dually eligible PACE participants upon entering a facility, in accordance with 42 CFR §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 Medicare and State Medicaid Capitation Payment

CMS makes a prospective monthly payment to the PO of a capitation amount for each Medicare participant in the payment area. Based on sections 1894(d) and 1853(n)(5) of the Act, prospective payments are made up of the pre-ACA county rate (calculated pursuant to section 1853(k)(1) of the Act), unadjusted for Indirect Medical Education (IME), and multiplied by the sum of the individual risk score and the organization frailty score. The following is a brief description of PACE payment and the differences between PACE payment and payment for Medicare Advantage plans below.

County Rates

The prospective payment rates for PACE are based on the applicable amount calculated under section 1853(k)(1) of the Act, unadjusted for IME.¹ 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. To determine whether a given year is a rebasing year, and for rules applicable to specific payment years, refer to the applicable Rate Announcement (available online at: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html>)

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 pursuant to section 1894(d)(3).

Effective CY 2006 and subsequent years for MA organizations, CMS makes advance monthly per capita payments for aged and disabled enrollees based on the bidding methodology established by the MMA. *See* section 1854 of the Act. POs are not required to bid, however, CMS also makes advance monthly per capita payments to POs for their enrollees, based on the PACE county benchmark amounts as the capitation rate.

Risk Adjustment

For the final payment rate, the county rate for the PO 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 a CMS-HCC model (community, long-

¹ The applicable amount is the pre-Affordable Care Act rate, which is phased-out under the Affordable Care Act for Medicare Advantage plans, with transition to a new benchmark methodology finalized nationwide in CY2017. Pursuant to section 1853(n)(5) of the Act, the applicable amount calculated under section 1853(k)(1) continues to apply for PACE.

term institutionalized, End-Stage Renal Disease (ESRD) or new enrollee), which is published in the annual Announcement of Calendar Year Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (Rate Announcement).

Section 1894(d)(2) of the Act requires CMS to take into account the frailty of the PACE population when making payments to POs. Therefore, a frailty factor is added to each individual's risk score for PACE payment. Risk adjustment predicts (or explains) the future Medicare expenditures of individuals based on diagnoses and demographics. Because risk adjustment may not explain all of the variation in expenditures for frail community populations, the frailty adjustment is used to predict the Medicare expenditures of community populations with functional impairments.

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 who responded to the survey the prior year. More information regarding the HOS-M can be found in section 10.30 in Chapter 10 of the PACE manual chapter, Quality Assessment and Performance Improvement, located online at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pace111c10.pdf>

Because the CMS-HCC model adequately predicts the costs of beneficiaries under age 55 or who are among the long-term institutionalized population, frailty adjustments are added to the risk scores for community-based and short-term institutionalized enrollees aged 55 and older. 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 POs 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, POs 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 POs are paid for the provision of outpatient prescription drugs to non-part D eligible PACE participants.

POs 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 POs comprises several pieces, including the risk adjusted direct subsidy, reinsurance payments, and risk sharing. With a few exceptions, Part D payments are made to POs in the same manner as to MA-PD and standalone PDP plans. The direct subsidy is risk adjusted. 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 PO’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 42 CFR §460.782(d).

4.7 Applicant Attestations

CENTERS FOR MEDICARE AND MEDICAID SERVICES CENTER FOR BENEFICIARY CHOICES CENTER FOR MEDICAID AND STATE OPERATIONS PROVIDER APPLICATION PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)	
NAME OF LEGAL ENTITY TRADE NAME (if different)	MAILING ADDRESS
AREA CODE TELEPHONE NO. EXTENSION	FAX
<i>CEO OR EXECUTIVE DIRECTOR:</i> 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:

APPROVED (TBD)

OMB Control Number: 0938-TBD

Expires: TBD

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

APPROVED (TBD)

OMB Control Number: 0938-TBD

Expires: TBD

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 (42 CFR §460.72)			
I.A. The PACE center must be designed, constructed, equipped, and maintained to provide for the physical safety of participants, personnel, and visitors.	<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"> • Fire exit system • Doorways that provide adequate width to allow easy access and movement of participants by wheelchair or stretcher; • Doorways and stairways that provide access free from obstructions at all times; • Lights and handrails in stairways, corridors, bathrooms, and at exits used by participants; • Toilets and stalls in the public bathrooms that are accessible to allow use by nonambulatory and handicapped participants, staff and visitors; 	<input type="checkbox"/> <i>MET</i> <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	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	<ul style="list-style-type: none"> • Evidence of compliance with the ADA (28 CFR Part 36 Title III). • Facility equipped with call lights for a communication system that alerts staff of participant problems in bathrooms, therapy areas, etc. • Design features to safeguard cognitively impaired clients who may wander (e.g. fences, door alarms, detector bracelets, etc.) <p>Written plan that outlines scheduled maintenance for the PACE center to include building maintenance.</p> <p>OTHER (SPECIFY)</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
<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"> • 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.; • The center must have lighting and sound levels in care areas, activity and dining rooms appropriate for individuals with vision, hearing, and cognitive impairments; • Proper ventilation; • Written policies and procedures for an effective pest control program to control household pests and rodents not limited to roaches, ants, flies, and mice; • Designated areas for smoking that are clearly marked and limited to participants and staff. 	<p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> N.A.</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
	<ul style="list-style-type: none"> • Posted signs that prohibit smoking while oxygen therapy is being administered and clearly designated universal oxygen signs. • Written policies and procedures to determine if or when participants may smoke without supervision. • 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; • Equipment stored in a manner to ensure participant’s safety at all times. OTHER (SPECIFY) 	<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"/> 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> <p>Team meetings</p> <p>Medical treatment and other care</p> <p>Therapeutic recreation</p> <p>Restorative therapies</p> <p>Socialization</p> <p>Personal care</p> <p>Dining</p> <p>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.</p>	<p>MET NOT MET</p> <p>MET NOT MET</p> <p>MET NOT MET</p> <p>MET NOT MET</p> <p>MET NOT MET</p> <p>MET NOT MET</p> <p>MET NOT MET</p> <p>MET</p>	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	OTHER (SPECIFY)	NOT MET MET NOT MET 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 manufacturer's recommendations	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. A written plan and monitoring program to check all contracts related to maintenance agreements.	<input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> MET	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
<p>and keep all equipment (mechanical, electrical, and patient care) free of defect. This includes any equipment in the patient's home.</p>	<p>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. Evidence of manufacturer's manuals for all equipment (mechanical, electrical, and patient care).</p> <p>OTHER (SPECIFY)</p>	<p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> Other (Specify and Attach)</p>	
<p>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>	<p>EVIDENCE OF COMPLIANCE WITH THE CURRENT EDITION OF THE LIFE SAFETY CODES.</p> <p>In addition have evidence of a: Fire Alarm System:</p> <ul style="list-style-type: none"> • Initiation • Notification • Control <ul style="list-style-type: none"> • Air Condition Shutdown • Automatic release of fire doors held open by magnetic devices <p>Staff training and Drills Fire evacuation Plans Fire Procedures</p> <p>OTHER (SPECIFY)</p>	<p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p>	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
		<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> <p>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;</p> <p>Written plan and procedures(s) for the periodic examination of all emergency drugs to confirm expiration date(s) and inventory control;</p> <p>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;</p> <p>At least one staff member during hours the center(s) have participant's present will be trained and certified in Basic Life Support (CPR).</p> <p>Verify that emergency drugs and emergency equipment is readily available, operating, and clean including:</p> <p>PORTABLE OXYGEN AIRWAYS</p>	<p>MET NOT MET</p> <p>MET NOT MET</p> <p>MET NOT MET</p> <p>MET NOT MET</p> <p>MET NOT MET</p>	

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>	<p>SUCTION EQUIPMENT PHARMACEUTICALS APPROPRIATE TO STABILIZE PARTICIPANTS.</p> <p>Written plan and procedures to manage nonmedical emergencies and any natural disasters affecting the center's geographic location, including:</p> <p>Method of containment of fire;</p> <p>Evacuation plans and routes;</p> <p>Adequate emergency lighting at exits and corridors;</p> <p>Plans for power outages, problems with water supply, and transfer of participants to other sites that meet their special needs;</p> <p>Periodic drills;</p> <p>Plan for assuring the health and safety of participants at home to ensure their continuing care needs will be met;</p>	<p>MET NOT MET</p> <p>MET NOT MET</p> <p>MET NOT MET</p> <p>MET NOT MET</p> <p>MET NOT MET</p>	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	<p>Facility structure and characteristics that will accommodate an expedient and safe evacuation of staff, participants, and visitors;</p> <p>OTHER (SPECIFY)</p>	<p>MET NOT MET</p> <p>MET NOT MET Other (Specify and Attach)</p>	
<p>INFECTION CONTROL (42 CFR §460.74)</p>			
<p>II. At a minimum, the PACE center must have an infection control plan that includes: A. Procedures</p>	<p>Written policies and procedures for the investigation, control, and prevention of infections including:</p> <p>A written OSHA Exposure Control Plan which includes the Universal Precautions and Bloodborne Pathogen exposure procedures for staff;</p>	<p>MET NOT MET</p> <p>MET</p>	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
<p>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 analyze the incidents of infection, to identify trends, and develop corrective actions related to the reduction of future incidents.</p>	<p>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);</p> <p>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.</p> <p>Written plans and procedures for the investigation, evaluation, resolution, and reporting of all incidences of staff and participant infection.</p> <p>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.</p> <p>Written plans and procedures for reporting required communicable diseases to the appropriate state and local officials.</p> <p>Plans and procedures for staff providing direct care to patients with infection(s);</p>	<p>NOT MET</p> <p>MET NOT MET</p> <p>MET NOT MET</p> <p>MET NOT MET</p> <p>MET NOT MET</p> <p>MET NOT MET</p> <p>MET NOT MET</p>	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	<p>Provision of adequate facilities and supplies necessary for infection control to include:</p> <p>Hand washing facilities and supplies;</p> <p>Laundry facilities and supplies;</p> <p>Isolation facilities and supplies</p> <p>Written plans and procedures for addressing how laundry will be handled. If the service is contracted out, written agreements to comply with the requirements.</p> <p>Written plans and procedures for the ongoing monitoring of the contractual agreement provisions for laundry and waste disposal.</p> <p>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 biohazardous wastes.</p>	<p>MET NOT MET</p> <p>MET NOT MET</p> <p>MET NOT MET</p> <p>MET NOT MET</p> <p>MET NOT MET NA</p> <p>MET</p>	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	OTHER (SPECIFY)	NOT MET Other (Specify and Attach)	
Transportation Services (42 CFR §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: Maintenance of transportation vehicles according to the manufacturer's</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 42 CFR §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>	<p>MET NOT MET</p> <p>MET NOT MET</p> <p>MET NOT MET NA</p> <p>MET NOT MET NA</p>	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
<p>recommendations. Transportation vehicles equipped to communicate with the PACE center. Training transportation personnel on the special needs of participants and appropriate emergency responses. As a part of the multi- disciplinary process, communicating relevant changes in the participant's care plans to transportation personnel.</p>	<p>Sufficient staff</p> <p>Written policies and procedures for the training and monitoring of drivers including:</p> <p>Proper transfer of nonambulatory and ambulatory participants;</p> <p>Proper use of equipment needed to transfer and secure participants;</p> <p>Emergency procedures during transfer, transport, and arrival of participants.</p> <p>Ability for communication between the driver and center during transportation activities.</p> <p>Evidence of written policies and procedures on the maintenance of vehicles utilized in the transport of participants.</p> <p>Written plans and procedures for communicating between the multidisciplinary team and the transport staff the needs of the participants being transported.</p>	<p>MET</p> <p>NOT MET</p> <p>MET</p> <p>NOT MET</p> <p>MET</p> <p>NOT MET</p> <p>MET</p> <p>NOT MET</p> <p>MET</p> <p>NOT MET</p> <p>MET</p> <p>NOT MET</p> <p>MET</p> <p>NOT MET</p>	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	<p>Written plans and procedures for monitoring the performance of all drivers.</p> <p>Written procedures to check or audit for the following information on the drivers: Current driver's license Record of any traffic violations or accidents that may constitute a potential hazard for the transport of participants.</p> <p>OTHER (SPECIFY)</p>	<p>MET NOT MET</p> <p>MET NOT MET</p> <p>Other (Specify and Attach)</p>	
Dietary Services (42 CFR §460.78)			
IV. PACE center is required to provide food that is nourishing, palatable, well-balanced, and meets acceptable safety	<p>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).</p> <p>Written policies and procedures that ensure the safe Delivery of food and nutritional supplements including:</p> <ul style="list-style-type: none"> • Safe procurement of food and nutritional supplements; 	<p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> N.A.</p> <p><input type="checkbox"/> MET</p>	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
<p>standards:</p> <p>A. Procure food from sources approved or considered satisfactory by Federal, State, Tribal or local authorities that have jurisdiction over the service area;</p> <p>B. Store, prepare, distribute, and serve food under sanitary conditions;</p> <p>C. Dispose of garbage and refuse properly</p>	<ul style="list-style-type: none"> • Safe storage of food and nutritional supplements both perishable and nonperishable to prevent contamination (at required temperatures – freezer below 0 degrees F or below and refrigerator 41 degrees or below); • Safe handling of food and nutritional supplements; • Safe preparation of food and medication, including policies for admixtures; • Safe and adequate water supply; • Safe and proper disposal of sewage; • Provisions for substitute foods or nutritional supplements; • Safe garbage storage and disposal; 	<p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p>	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	<ul style="list-style-type: none"> • Training of staff in safe food delivery; and • Written policies and procedures for emergency food supplies and emergency nutritional supplements. <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"/> 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)	
Bill of Rights (42 CFR §460.110)			
V. The PACE	Written policies and procedures governing the participant Bill of Rights including:	<input type="checkbox"/> MET	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
<p>organization must have written policies and implement procedures to ensure that the participant, his or her representative, and staff understand their rights.</p>	<ul style="list-style-type: none"> • The parameters on the use of physical or chemical restraints; • The reporting of mental or physical abuse or neglect. <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. <u>Evidence of compliance with State requirement, if any, for specific criteria of the principle language</u></p> <p>The participant Bill of Rights should be in a large print for the elderly to read.</p> <p>Written policies and procedures to respond to and Rectify a violation of a participant's rights.</p> <p>OTHER (SPECIFY)</p>	<p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p>	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
		<input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> OTHER (Specify and Attach)	
Personnel Qualifications (42 CFR §460.64)			
VI. The PACE center must have qualified staff to provide care to its frail elderly participants.	<p>Signed contracts for all contractors and contracted personnel by the time the PACE center becomes operational.</p> <p>Written position descriptions for all staff (employees and contractors).</p> <p>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.</p> <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</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	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	<p>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)	
TRAINING AND COMPETENCY (42 CFR §460.66 AND 42 CFR §460. 71)			
VII. A. The PACE organization must provide training to maintain and improve the skills and knowledge of each staff member with respect to the individual's specific duties that results in	<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"> • 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"> • Initial hires and ongoing skills demonstration; 	<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>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"> • Skills demonstration method of evaluation based on standard protocols; • Competent evaluator (including peer evaluator); • Skills that reflect scope of practice and appropriate for the PACE center, home setting and level of care. • Training should be specific and within the scope of practice. To include at least the following: <ul style="list-style-type: none"> • Training and demonstrated competency on the transport of nonambulatory participants for drivers and any other applicable staff; • Training and demonstrated competency on all emergency equipment and all other equipment necessary for the performance of his or her specific position; • Training and demonstrated competency on center emergency procedures; 	<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
	<ul style="list-style-type: none"> • Training and demonstrated competency on restraint use; • Training and demonstrated competency on participant rights, including dignity and privacy, to all participants; • Training and demonstrated competency in response to participant grievances or center quality improvement activities; and • Training and demonstrated competency in therapeutic communication specific to the PACE setting and population. <p>Written training manual for personal care attendants to ensure that they exhibit competency in basic skills for providing personal care, including:</p> <ul style="list-style-type: none"> • How to maintain a clean, safe and healthy environment; • Appropriate and safe techniques in personal hygiene and grooming; • Safe transfer techniques and ambulation; 	<ul style="list-style-type: none"> <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
	<ul style="list-style-type: none"> • Observation, reporting, and documentation of patient status and the care or service furnished. • Training in therapeutic communication specific to the PACE setting and population; and • Other elements consistent with their assigned duties. <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"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> Other	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
		(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"> <input type="checkbox"/> ADHC <input type="checkbox"/> HH <input type="checkbox"/> Clinic <input type="checkbox"/> HMO <input type="checkbox"/> Ambulatory Care Center <input type="checkbox"/> Other - specify <p>Written plans and procedures regarding the safeguarding of participant data and records according to HIPAA compliance for security (electronic and paper).</p> <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>	<ul style="list-style-type: none"> <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>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>	<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"/> NA <input type="checkbox"/> Other (Specify and Attach)	
General Safety Requirements			
IX.	Evidence of state pharmacy licensure.	<input type="checkbox"/> MET	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
Overall PACE center safety requirements	<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> <p>OTHER (SPECIFY)</p>	<input type="checkbox"/> NOT MET <input type="checkbox"/> N.A. <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	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
		(Specify and Attach)	

This version completed October 28, 2003