

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 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 alternative care setting (ACS). An ACS can be any physical location in the PACE organization'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 certain 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 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 legislative history of the PACE program between 1999 and 2006, please see 71 FR 71244 through 71248 (Dec. 8, 2006).

CMS issued a final PACE rule (CMS-4168-F), effective August 2, 2019, which updated and modernized the PACE program. This final rule codified CMS' existing practice of relying on automated review systems for processing initial applications to become a PACE organization and expansion applications for existing PACE organizations. In addition, the final rule modified the PACE regulations to eliminate the need for PACE organizations to request waivers for a number of the most commonly waived provisions.

CMS finalized a PACE rule (CMS-4190-F2 (86 FR 5864)), applicable January 1, 2022. This rule largely impacted the participant rights aspect of the application by adding 3 new distinct rights as well as requirements related to participant appeals. The rule also included new service determination request provisions, which enable PACE participants to request initiation of a service, modification of an existing service or continuation of a service that a PACE organization recommends be discontinued or reduced

CMS issued a final rule ([CMS-4201-F \(88 FR 22120\)](#)), applicable January 1, 2024. CMS amended the definition of contract year at § 460.6 to state that a PACE organization's initial contract year may be 19 to 30 months, as determined by CMS, but in any event will end on December 31. Additionally, CMS updated requirements for contracted services that PACE organizations use, both administrative or care-related, to furnish services to participants;

CMS finalized updates to the PACE program under a final rule ([CMS-4201-F3 and CMS-4205-F \(89 FR 30448\)](#)), applicable January 1, 2025. Updates in this rule include, incorporating an evaluation of past performance into the review of applications submitted by PACE organizations that seek to offer a PACE program or expand an approved program by adding a geographic service area and/or PACE center site or sites; defining what constitutes a complete and valid PACE application; compliance actions for failure to comply with the terms of the PACE program agreement; updates to the required PACE participant rights; and updates to the required procedures for grievances and appeals for PACE participants.

1.2 Technical Support

CMS provides training information available on the CMS website at: <https://www.cms.gov/Medicare/Health-Plans/PACE/Overview>. This includes both an overview of the PACE application process as well as training to assist applicants with navigating the Health Plan Management System (HPMS), which is the system used by applicants to prepare and submit their electronic applications. All applicants are strongly encouraged to view these trainings prior to initiating the application process.

CMS 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 inquiries to the PACE portal at: <https://PACE.lmi.org>. Please note: this is a webpage, not an email address.

1.3 The Health Plan Management System (HPMS)

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.

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.

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 must complete a nonbinding NOIA in order to submit an initial PACE application to be approved as a PACE organization. The NOIA form is available on the CMS website at: <https://www.cms.gov/Medicare/Health-Plans/PACE/Overview>. The completed form must be submitted to the PACE portal at: <https://PACE.lmi.org>.

To ensure adequate time for processing, applicants should submit the completed NOIA to the PACE portal during the first month of the quarter in which the applicant intends to submit the application. **(Applications must be created, completed and submitted within the same quarter to HPMS.)** NOIAs that are not submitted timely may result in an organization's inability to submit the application during the desired quarterly cycle. Upon submission of the completed NOIA form to CMS, the organization will be assigned a pending contract number (H number) to use throughout the application and subsequent operational processes. This contract number starts with an H and is followed by 4 numbers (Hxxxx).

Once a contract number is assigned, the applicant should request a CMS User ID, which is needed to access CMS systems. To request a user ID, follow the "Instructions for Requesting Plan Access via EFI" link in the **Downloads** section of the following website: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/UserIDProcess.html>. This process may take 2-4 weeks, so applicants must allow sufficient time to obtain access and complete the application prior to the quarterly submission deadline. Upon approval of the CMS User ID request, the applicant will receive a

CMS User ID(s) and password(s) for HPMS access.

Note that a NOIA is not required of existing, operational PACE organizations that seek to submit an expansion application. However, expansion applicants should inform their CMS Account Managers of any plans to submit a service area expansion application.

1.4.1 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 §460.20, if CMS denies an application, including for past performance deficiencies (§460.18), CMS must notify the entity in writing of the basis for the denial and the process for requesting reconsideration of the denial.

2 INSTRUCTIONS

2.0 Overview

Applicants must complete the PACE initial and service area expansion (SAE) application using HPMS as instructed. All documentation must contain the appropriate CMS-issued contract (“H”) number. Applications are accepted on a quarterly basis, on a designated day, which is generally the last Friday in March, June, September and December, with possible modification to account for a holiday. While applications may be created at any time during a specific quarterly cycle, the completed application (i.e., attestation responses and all uploaded documentation, as required) may not be transmitted until the applicant hits the “Final Submit” button on the designated day. CMS provides the submission dates for a given year through an HPMS blast or email in the early part of the year and includes an announcement in HPMS to indicate when the next cycle applications are due.

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.

Applicants should carefully enter their service area into HPMS and ensure that it aligns with the counties and/or zip codes that they have been granted by the state.

The address entered into HPMS for the PACE center must be the physical address for the center. Placeholder addresses will not be accepted. Throughout this application, applicants are asked to provide various documents 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 associated with initial and SAE applications is also included in Section 2.2.

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; applicants are required to comply with all applicable requirements of the regulations. Applicants must read HPMS memos and visit the CMS website periodically to stay informed about new or revised guidance documents.

2.1 Types of Applications

Initial Applications are for:

- Applicants who are seeking to become a PACE organization 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. This includes an expansion of the currently-approved geographic service area and/or the addition of a new PACE center site.

2.2 Chart of Required Attestations and Uploads

This chart (Chart 1) describes the required attestations and uploads for both initial PACE and SAE applications. Note that SAE applicants must generally respond to the same attestations, as well as upload all documents required of initial applicants. (See Section 2.3.1, below, regarding upload submission instructions and information specific to SAE 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	X	X
Governing Body	3.3	X	X	X	X
Fiscal Soundness	3.4	X	X	X	*
Marketing	3.5	X	X	X**	X** (as applicable)
Explanation of Rights	3.6	X	X	X	X
Grievance	3.7	X	X	X	X
Service Determination Process	3.8	X	X		
Appeals	3.9	X	X	X	X
Enrollment	3.10	X	X	X	X
Disenrollment	3.11	X	X	X	X
Personnel Compliance	3.12	X	X		
Program Integrity	3.13	X	X		
Contracted Services	3.14	X	X		
Required Services	3.15	X	X		
Service Delivery	3.16	X	X		
Infection Control	3.17	X	X		
Interdisciplinary Team	3.18	X	X		
Participant Assessment	3.19	X	X		
Plan of Care	3.20	X	X		
Restraints	3.21	X	X		
Physical Environment	3.22	X	X		
Emergency and Disaster Preparedness	3.23	X	X		
Transportation Services	3.24	X	X		
Dietary Services	3.25	X	X		
Termination	3.26	X	X	X	X
Maintenance of Records & Reporting Data	3.27	X	X		
Medical Records	3.28	X	X		
Quality Improvement Program	3.29	X	X	X	X
State Attestations	3.30	X	X	X	X
Waivers	3.31	X	X	X (as applicable)	X (as applicable)
Application Attestations	3.32	X	X	X	X
State Readiness Review	3.34	X	X	X***	X*** (as applicable)

* Financial documentation is not a requirement of SAE applicants. However, applicants may be asked to

provide specific information as part of the Request for Additional Information (RAI) process if CMS is unable to verify that the applicant is maintaining a fiscally sound operation.

** Marketing materials for both initial and SAE applications are captured separately, via the HPMS PACE marketing module. Applicants must upload marketing materials in the HPMS marketing module for CMS/State review and approval following application submission. Additional information regarding the marketing materials associated with an application may be found in Section 3.5 of this application.

*** The State Readiness Review is required but may or may not be uploaded as part of the initial submission of the application; the State Readiness Review may be uploaded after the initial application submission, subsequent to CMS's RAI.

2.3 Document (Upload) Submission Instructions

Required upload documents must generally be grouped together in a zipped file before uploading. The Readme files for both the PACE and Part D applications (found in the appropriate download templates) details which files to group together and which are to be uploaded individually. Note that each succeeding upload overwrites any previous upload. Therefore, when re-uploading a grouped file, applicants **MUST** include ALL files in the group in the re-upload.

In addition, the Readme Files provide Naming Conventions for uploaded files. PACE applicants must use these naming conventions, where applicable, and be sure to include the assigned H number in the file name of all submitted documents.

2.3.1 Document (Upload) Instructions Specific to SAE Applications

Generally, the same attestation and upload requirements are required of both initial and SAE applicants. One key exception is Section 3.4 (Fiscal Soundness), which includes different attestation requirements for initial and SAE applicants. In addition, while there is no required financial upload for a PACE SAE application, an applicant may be asked to provide specific information as part of a request for additional information. Documentation submitted in conjunction with initial and SAE applications will be reviewed and incorporated as part of the amended program agreement following approval of the application.

All applicants must upload a signed "State Assurances" document provided by an authorized official of the State Administering Agency (SAA) to demonstrate that the SAA supports the application. All initial applications and any SAE application that includes the addition of a new PACE center require a State Readiness Review (SRR) of the new center. Note that SAE applications that do not include a new PACE center site generally do not require a readiness review; however, the SAA must consider whether the existing PACE center has the capacity to adequately serve new potential participants who reside in the proposed expanded geographic area. SAAs may vary in their requirements for approval of the SAE under these circumstances.

NOTE regarding SAE applications: Active PACE organizations may not submit a service area expansion application if an application is currently pending. PACE organizations that seek to submit another expansion application must wait until CMS has made a final

determination regarding the pending application before submitting another as part of a subsequent quarterly cycle. Therefore, organizations should carefully consider expansion proposals and plan accordingly when submitting expansion applications.

2.4 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

3.0 Administrative Requirements – Trial Period (SAE applicants only)

The purpose of this section is to ensure that SAE applicants have successfully completed the first trial period audit in order to be able to proceed with the submission of a SAE application consistent with the requirements of 42 CFR §460.12.

A. In HPMS, complete the attestations and applicable uploads below:

RESPOND ‘YES’ OR ‘NO’ TO THE FOLLOWING STATEMENT: TRIAL PERIOD	YES	NO
<p>1. Applicant acknowledges that the first trial period audit has been successfully completed.</p> <p>(If the response is “No,” the applicant may not proceed with the SAE application because CMS and the State Administering Agency (SAA) will only approve a service area expansion or PACE center site expansion after the PACE organization has successfully completed its first trial period audit and, if applicable, has implemented an acceptable corrective action plan per 42 CFR §460.12(d).)</p>		

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 §460.12, §460.70, and §460.98.

A. In HPMS, complete the attestations and applicable uploads 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 §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 §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 (including the address of the PACE center facility), 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. Service area expansion applications that include a geographic expansion must clearly distinguish the proposed expansion area from the currently approved service area.

Note: The map must be developed in accordance with 42 CFR §460.12, §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 attestations and applicable uploads 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 (§460.60(a)).			
RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: LEGAL ENTITY AND ORGANIZATIONAL STRUCTURE	YES	NO	N/A
3. Applicant agrees that the Medical Director is responsible for delivery of participant care, clinical outcomes and implementation and oversight of the quality improvement program (§460.60(b)).			
4. Applicant agrees to maintain an up-to-date organizational chart indicating the persons and titles of all officials in the PO (§460.60(c)).			
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 (§460.60(c)(3)).			
7. For any planned change in ownership, the applicant agrees to comply with all requirements in 42 CFR part 422, subpart L, and must notify CMS and the SAA, in writing, at least 60 days before the anticipated effective date of the change (§460.60(d)).			
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.			
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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 attestations and applicable uploads below:

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: GOVERNING BODY	YES	NO
<p>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:</p> <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 • Quality improvement program. (see §460.62(a)(7)) 		
<p>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 (§460.62(b)).</p>		

<p>3. Applicant agrees to appoint a participant representative to act as a liaison between the governing body and Participant Advisory Committee and present participant issues from the Participant Advisory Committee to the governing body per §460.62(c).</p>		
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B. In the Documents Section, upload a current list of the governing body members/board of directors and their titles and 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 §460.60(a).

3.4 Fiscal Soundness

3.4.1 Initial Application

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 attestations and applicable uploads below:

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: FISCAL SOUNDNESS	YES	NO	N/A
<p>1. Applicant agrees to maintain a fiscally sound operation as specified in 42 CFR §460.80(a)(1-3):</p> <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 SAA. 			
<p>2. Applicant agrees to provide CMS a copy of the signed "Subordinated/Guaranteed Debt Attestation" form for each financial reporting period.</p>			
<p>3. Applicant agrees to upload a documented plan in the event of insolvency as specified in 42 CFR §460.80(b).</p>			
<p>4. Applicant agrees to provide CMS and the SAA accurate financial reports as specified in 42 CFR §460.204.</p>			
<p>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.</p>			
<p>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</p>			

supporting documentation necessary to demonstrate how the applicant meets these requirements.			
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- 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/Guaranteed 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. Guaranteed debt is defined as secured debt in which another entity promises to pay a loan or other debt if the organization that borrowed the money fails to pay. If subordinated/guaranteed debt is identified by the PACE organization (legal entity), it should be included in the total PACE liabilities and the amount of subordinated/guaranteed 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/guaranteed 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).

3.4.2 Service Area Expansion Application

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. CMS reserves the right to request additional financial information such as the most recent audited annual financial statements and most recent unaudited financial statements, as it sees fit to determine if the applicant is maintaining a fiscally sound operation.

A. In HPMS, complete the attestations and applicable uploads below:

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: FISCAL SOUNDNESS	YES	NO	N/A
<p>1. Applicant maintains a fiscally sound operation as specified in 42 CFR §460.80(a)(1-3):</p> <ul style="list-style-type: none"> • Total assets greater than total unsubordinated 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 SAA. 			

Note: CMS will confirm the attestation response by reviewing the most recent audited annual financial statements submitted by the applicant through the Fiscal Soundness Module in HPMS. If the most recent audited annual financial statements in the HPMS fiscal soundness module do not demonstrate that the applicant is maintaining a fiscally sound operation by at least maintaining total assets greater than total unsubordinated liabilities, the applicant must demonstrate that it is meeting fiscal soundness requirements and upload either:

1. The final audited annual financial statements for the most recent fiscal year end, demonstrating the applicant is maintaining a fiscally sound operation by at least maintaining a positive net worth (total assets greater than total unsubordinated liabilities) in accordance with 42 CFR Section 460.80(a)(1); or
2. The most recent quarterly or annual financial statements and include an opinion (such as a letter, not a full audit) from the applicant's independent auditor confirming that the organization's most recent quarterly or annual financial statements are meeting CMS's fiscal soundness requirement by at least maintaining a positive net worth (total assets exceed total unsubordinated liabilities) in accordance with 42 CFR Section 460.80(a)(1).

B. In the Documents Section, upload the most recent independently audited financial statements.

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 legal entity.

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 the PACE Marketing Guidelines.

A. In HPMS, complete the attestations and applicable uploads below:

RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: MARKETING	YES	NO
1. Applicant agrees to follow PACE 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. 		
2. Applicant agrees that the following information on restriction in services is included in their marketing materials: <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. 		
3. Applicant agrees that the marketing material is free of inaccuracies, misleading information, or misrepresentations.		

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: MARKETING	YES	NO
<p>4. Applicant agrees to make marketing materials available to prospective and current participants in English and in any other principal languages of the community as determined by the State in which the PACE organization is located (in the absence of a State standard, a principal language of the community is any language that is spoken by at least 5 percent of the individuals in the PACE organization's service area), and in Braille, if necessary, per 42 CFR §460.82(c).</p>		
<p>5. Applicant agrees to submit marketing material, as outlined in the PACE Marketing Guidelines, to the HPMS module and obtain CMS Regional Office and SAA 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):</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; • Marketing by any individual or entity that is directly or indirectly compensated by the PACE organization based on activities or outcomes unless the individual or entity has been appropriately trained on PACE program requirements; and • Unsolicited door-to-door marketing or other unsolicited means of direct contact. 		
<p>7. 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: PACE organizations may begin submitting marketing materials for review after the application has been submitted and the PACE organization gains access to the HPMS Marketing Module. If a PACE organization does not have an executed contract with CMS, any submitted and approved marketing materials will be considered as conditionally approved, pending the outcome of the application review. Initial PACE applicants may not

begin marketing until they have been approved and have received a copy of their program agreement signed by all parties; SAE applicants may not begin marketing in the expanded geographic area, as applicable, until the SAE has been approved and the PACE organization has received the amended program agreement.

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 §460.82, §460.110, §460.112, §460.116, and §460.118.

A. In HPMS, complete the attestations and applicable uploads 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 designated representative, if any, understand their participant rights as specified in §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 §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 §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 as determined by the State in which the PACE organization is located (in the absence of a State standard, a principal language of the community is any language that is spoken by at least 5 percent of the individuals in the PACE organization's service area), and in Braille, if necessary, per §460.82(c); and • Display the PACE participant's rights in a prominent place in the PACE center as specified in §460.116(c). 		
5. Applicant ensures that their procedures respond to and rectify a violation of a participant's rights in §460.118.		
6. Applicant agrees to explain advance directives to participants, and establish them, if the participant so desires, as specified in §460.112(e)(3).		
7. Applicant agrees to fully explain the PACE organization’s palliative care, comfort care, and end-of-life care services including providing written information and treatment options		

and obtaining written consent from the participants or designated representatives prior to initiating such services, as required under §460.112(e)(2).		
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In the Documents Section, upload a copy of your Participant Bill of Rights. Please note the PACE Participant Rights template document, which may be found at: <https://www.cms.gov/Medicare/Health-Plans/PACE/Overview>.

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, designated representatives, or caregivers to express dissatisfaction with service delivery or the quality of care furnished without fear of discrimination or reprisal, and regardless of whether remedial action is requested, consistent with the requirements of 42 CFR §460.120 Grievances may be between participants and the PACE organization or any other entity or individual through which the PACE organization provides services to the participant.

A. In HPMS, complete the attestations and applicable uploads below:

YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: GRIEVANCES	YES	NO
1. Applicant agrees to have a formal written process to promptly identify, document, investigate, and resolve medical and non-medical grievances by participants, their family members designated representatives, or caregivers that meets all requirements in §460.120.		
2. Applicant agrees to provide participants with written information on the grievance process in understandable language upon enrollment, and at least annually thereafter, in accordance with §460.120(c)(1-3).		
3. Applicant agrees to conduct a thorough investigation of all distinct issues within the grievance when the cause of the issue is not already known (§460.120(f)).		
4. Applicant agrees to take action to resolve the grievance based on the results of its investigation as expeditiously as the case requires, but no later than 30 calendar days after the date the PACE organization receives the oral or written grievance, and to notify the individual who submitted the grievance of the grievance resolution as expeditiously as the case requires, but no later than 3 calendar days after the date the PACE		

organization resolves the grievance (§460.120(g)).		
5. Applicant agrees to follow all grievance resolution notification requirements including who must be notified, what information must be included in notifications, and all requirements under §460.120(h).		
6. Applicant agrees to provide continuing care and furnish all required services to participants during the grievance process (§460.120(i)).		
7. Applicant agrees to develop and implement procedures to maintain the confidentiality of a grievance, including protecting the identity of all individuals involved in the grievance from other employees and contractors when appropriate (§460.120(j)).		
8. Applicant agrees to establish and implement a process to document, track, and maintain records related to all processing requirements for grievances received both orally and in writing, and to make these records, except for information deemed confidential, available to the interdisciplinary team to ensure that all members remain alert to pertinent participant information ((§460.120(k)).		
9. Applicant agrees to aggregate and analyze the information collected related to grievances, for purposes of its internal quality improvement program ((§460.120(l)).		

B. In the Documents Section, upload a copy of your policies and procedures for grievances.

3.8 Service Determination Process

The purpose of this section is to ensure that all PACE applicants have procedures for identifying and processing service determination requests in accordance with the requirements at 42 CFR §460.121.

A. In HPMS, complete the attestations and applicable uploads below:

RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: APPEALS	YES	NO
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<p>1. Applicant agrees to have formal written procedures for identifying and processing service determination requests consistent with specific requirements at §460.121(a).</p>		
<p>2. Applicant agrees to accept service delivery determination requests from the participant, participant’s designated representative, or participant’s caregiver either orally or in writing (§460.121(c) and §460.121(d)(1)).</p>		
<p>3. Applicant agrees that an individual may make a service determination request to any employee or contractor that provides direct care to the participant in the participant's residence, the PACE center, or while transporting the participant (§460.121(d)(2)).</p>		
<p>4. Applicant agrees to process service determination requests in accordance with §460.121(e) – (i) and §460.121(l).</p>		
<p>5. Applicant agrees to provide the participant or the designated representative with notification of the decision as required in §460.121(j).</p>		
<p>6. Applicant agrees to provide the approved service as expeditiously as the participant's condition requires, taking into account the participant's medical, physical, emotional, and social needs in accordance with (§460.121(k)).</p>		
<p>7. Applicant agrees to establish and implement a process to document, track, and maintain records related to all processing requirements for service determination requests received both orally and in writing. These records must be available to the interdisciplinary team to ensure that all members remain alert to pertinent participant information (§460.121(m)).</p>		

3.9 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, §460.122, and §460.124.

A. In HPMS, complete the attestations and applicable uploads below:

RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: APPEALS	YES	NO
<p>1. Applicant agrees to have a formal written process, with specified timeframes for response, to address noncoverage of or nonpayment of a service, that includes, at a minimum, procedures for the following, as specified in §460.122(a), and 42 CFR §460.122(c):</p> <ul style="list-style-type: none"> • Written denials of coverage or payment are prepared and processed timely, as provided in §460.122(c)(1); • How a participant or designated representative files an appeal, including procedures for accepting oral and written appeal requests, per §460.122(c)(2); • Documentation of participant's appeal per §460.122(c)(3); • Review of an appeal by an appropriate third party reviewer or committee, per §460.122(c)(4); • The distribution of written or electronic materials to the third party reviewer or committee as specified in §460.122(c)(5); • Responses to, and resolution of, appeals as expeditiously as the participant's health condition requires, but no later than 30 calendar days after the organization receives an appeal, per §460.122(c)(6); and • Maintenance of confidentiality of appeals, per §460.122(c)(7). 		
<p>2. Applicant agrees to provide participants written information on the appeals process upon enrollment, at least annually thereafter, and whenever the interdisciplinary team (IDT) denies a service determination request or request for payment as specified in §460.122(b) and §460.124.</p>		
<p>3. Applicant agrees to give all parties involved in the appeal a reasonable opportunity to present evidence related to the dispute in person, and in writing as specified in §460.122(d).</p>		

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: APPEALS	YES	NO
<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):</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 during the appeals process as specified in §460.122(e)(2).</p>		
<p>6. 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 or maintain maximum function could be seriously jeopardized, absent provision of the service in dispute as specified in §460.122(f)(1).</p>		
<p>7. 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 §460.122(f)(2).</p>		
<p>8. 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 §460.122(f)(3):</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>9. Applicant agrees to give all parties involved in the appeal appropriate written notification of the decision to approve or deny the appeal that meets specified requirements at §460.122(g).</p>		

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: APPEALS	YES	NO
10. 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, per §460.122(h).		
11. Applicant agrees to maintain, aggregate and analyze information on appeal proceedings, and use this information in its internal quality improvement program as specified in §460.122(i).		
12. Applicant agrees to inform participants in writing of their additional appeal rights under Medicare, Medicaid, or both if the participant is dually eligible, in accordance with §460.124(a), §460.124(b) and §460.124(c).		

B. In the Documents Section, upload your policies and procedures for the appeals process. The policies and procedures should specify whether the timeframes for responding to appeals are calendar days or business days.

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

C. In the Documents Section, upload your policies and procedures regarding participants' additional appeals rights under Medicare and/or Medicaid, including the process for filing further appeals. The policies and procedures should specify whether the timeframes for responding to appeals are calendar days or business days.

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

3.10 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 attestations and applicable uploads 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 §460.150(b), 42 CFR §460.150(c) and §460.150(d): <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 at the time of enrollment without jeopardizing his or her health or safety as determined by the SAA 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. 		
2. Applicant agrees to comply with the requirements of §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 §460.154 and §460.82		

<p>RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: ENROLLMENT</p>	<p>YES</p>	<p>NO</p>
<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 §460.152(a):</p> <ul style="list-style-type: none"> • Explains the PACE program, using a copy of the enrollment agreement described in §460.154; • Informs participant that PACE is the sole service provider; • Informs participant that PACE guarantees access to services, but not access to specific providers; • Provides a list of employed and most current list of 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 from potential participant to allow the PACE organization 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 Medicaid state plan; and • Requires assessment by the PACE staff to determine if the potential participant 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 §460.152(b):</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 reason for the denial; and • Notify CMS and SAA in the form and manner specified by CMS and make documentation available for review. 		

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: ENROLLMENT	YES	NO
<p>6. Applicant agrees to give the enrolled participant the following items after the enrollment agreement is signed as specified in §460.156(a):</p> <ul style="list-style-type: none"> • A copy of the enrollment agreement; • A PACE membership card; that indicates the individual is a PACE participant and includes the PACE phone number; and • Emergency information to be posted in the participant's residence identifying the individual as a PACE participant and explaining how to access emergency services. 		
<p>7. Applicant agrees to submit participant information to CMS and SAA in accordance with established procedures as specified in §460.156(b).</p>		
<p>8. Applicant agrees to meet the following requirements when making necessary changes in the enrollment agreement as specified in §460.156(c):</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 §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 §460.160(a):</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 Medicaid state 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 §460.160(b)(1).</p>		

RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: ENROLLMENT	YES	NO
12. Applicant agrees to continue enrollment for the participant who no longer meets the state Medicaid nursing facility level of care requirements, 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 §460.160(b)(2).		
13. Applicant agrees to work in consultation with the SAA in making a determination of deemed continued eligibility as specified in §460.160(b)(3): <ul style="list-style-type: none"> • Make a determination of “deemed continued eligibility” based on a review of the participant’s medical record and plan of care by applying the SAA established criteria. Criteria used to make the determination must be specified in the program agreement. 		

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

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

- C. In the Documents Section, upload any additional enrollment criteria. If not applicable, please enter N/A in the required document upload template document.

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.

Note: Applicants are to submit a copy of the enrollment agreement, consistent with the requirements stipulated in §460.154 and §460.82, to the HPMS PACE marketing module for review and approval.

3.11 Disenrollment

The purpose of this section is to ensure that all PACE applicants follow the voluntary and involuntary disenrollment requirements consistent with 42 CFR §460.162 §460.164, §460.166, §460.168, §460.170, and §460.172. PACE organizations must facilitate participants’ reinstatement in the PACE program, when applicable, or other Medicare and Medicaid Programs for which they are eligible.

A. In HPMS, complete the attestations and applicable uploads below:

RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: DISENROLLMENT	YES	NO
<p>1. Applicant agrees to meet the following requirements regarding documentation for disenrollment as specified in §460.172:</p> <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 quality improvement program to review documentation on voluntary disenrollment. 		
<p>2. Applicant agrees to execute disenrollment for any participant initiating voluntary disenrollment from the program without cause at any time as specified in §460.162, effective the first day of the month following the date the participant's notice of voluntary disenrollment is received.</p>		
<p>3. Applicant agrees that its employees or contractors do not engage in any practice that would reasonably be expected to have the effect of steering or encouraging disenrollment of participants due to a change in health status, per §460.162(c).</p>		

RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: DISENROLLMENT	YES	NO
<p>4. Applicant agrees that involuntary disenrollment of a participant will only be initiated for any of the following reasons as specified in §460.164(b) and §460.164(c), and is effective on the first day of the next month that begins 30 days after the day the PACE organization sends notice of the disenrollment to the participant, per §460.164(a):</p> <ul style="list-style-type: none"> • Participant, after a 30-day grace period, fails to pay, or to make satisfactory arrangements to pay, any premium due the PACE organization; • Participant, after a 30 day grace period, fails to pay, or make satisfactory arrangements to pay any applicable Medicaid spend down liability or any amount due under the post-eligibility treatment of income process, as permitted under §§460.182 and 460.184; • 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 not 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 or participant's caregiver 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 their individual plan of care or terms of the enrollment agreement. 		
<p>5. 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 §460.164(d) that includes:</p> <ul style="list-style-type: none"> • Reason for the proposed involuntary disenrollment; and • Efforts to remedy the situation. 		

RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: DISENROLLMENT	YES	NO
6. 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 §460.164(e).		
7. 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 §460.164(f).		
8. Applicant agrees to take the following actions in executing the disenrollment as specified in §460.166(a), and §460.166(b) (2): <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 dually eligible participants); • Give reasonable advance notice to the participant; and • Continue to deliver PACE services to the participant until the date enrollment is terminated. 		
9. 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 §460.166(b)(1).		
10. Applicant agrees to take the following actions to facilitate a participant's reinstatement in other Medicare and Medicaid programs after disenrollment as specified in §460.168(a) (b): <ul style="list-style-type: none"> • Make appropriate referrals and transmit copies of medical records to new providers within 30 days; and • Work with CMS and SAA to reinstate the participant in other Medicare and Medicaid programs for which the participant is eligible. 		
11. Applicant agrees to permit a previously disenrolled participant to be reinstated in the PACE program as specified in §460.170(a).		

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: DISENROLLMENT	YES	NO
12. Applicant agrees that a participant being disenrolled for failure to pay the premium will remain enrolled with no break in coverage if the participant pays the premium before the effective date of disenrollment as specified in §460.170(b).		

B. In the Documents Section, upload a copy of the Voluntary Disenrollment policies and procedures.

C. In the Documents Section, upload a copy of the Involuntary Disenrollment policies and procedures.

3.12 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 attestations and applicable uploads below:

<p>RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: PERSONNEL COMPLIANCE</p>	<p>YES</p>	<p>NO</p>
<p>1. Applicant ensures that staff having direct participant contact, (employed and contracted) meet the following conditions as specified in §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 or, if the individual has less than 1 year of experience but meets all other requirements specified in 42 CFR §460.64, must receive appropriate training from the PACE organization on working with a frail or elderly population upon hiring; • Meet a standardized set of competencies for the specific position description established by the applicant prior to working independently; and • Be medically cleared for communicable diseases through either a physical exam or a qualifying risk assessment as specified in 460.64(a)(5)(iii), 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 §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 §460.66.</p>		
<p>3. Applicant agrees to provide each staff (employed and contracted) with an orientation that includes, at a minimum, 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 as specified in §460.71(a)(1).</p>		

RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: PERSONNEL COMPLIANCE	YES	NO
<p>4. 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 §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 §460.71(a)(3).</p>		
<p>5. 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 §460.71(a)(4).</p>		
<p>6. Applicant ensures that all staff (employed and contracted) furnishing direct participant care services meet the following as specified in §460.71(b):</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 §460.68(a), regarding persons with criminal convictions; • Have verified current certifications or licenses for their respective positions; • Are medically cleared for 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 PACE organization. 		
<p>7. Applicant agrees to develop a training program as specified in §460.71(c) 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 §460.71(d).</p>		

3.13 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 attestations and applicable uploads below:

RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: PROGRAM INTEGRITY	YES	NO
<p>1. Applicant agrees to comply with requirements of §460.68 (a) and attests that it will not employ individuals or contract with organizations or individuals:</p> <ul style="list-style-type: none"> • 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; • Whose contact with participants would pose a potential risk because the individual has been convicted of one or more criminal offenses related to physical, sexual, drug or alcohol abuse or use, as determined by the PACE organization; • Who have been found guilty of abusing, neglecting, or mistreating individuals by a court of law or who have had a finding entered into the state nurse aide registry concerning abuse, neglect, mistreatment of residents, or misappropriation of their property; or • Who have been convicted of specific crimes for any offense described in section 1128(a) of the Social Security Act. 		
<p>2. Applicant agrees to comply with requirements of §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 §460.68(b) and (c).</p>		

3.14 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 attestations and applicable uploads 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 PACE organization except for emergency services as specified in §460.70(a), and §460.100.		
2. Applicant agrees that the organization will have a written contract with all required medical specialties identified in §460.70(a)(1) prior to enrolling participants and on an ongoing basis.		
3. 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 §460.70(b)(1), §460.70(b)(2), §460.98, and §460.100: <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 quality improvement activities; and • Contractors must be accessible to participants and located either within or near the PO's service area. 		
4. Applicant agrees that the organization designates an official liaison to coordinate activities between contractors and the organization as specified in §460.70(b)(3).		
5. 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 §460.70(c).		
6. 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.		
7. Applicant agrees that each contract contains the requirements as specified in §460.70(d).		

<p>8. Applicant acknowledges it cannot contract with another entity to furnish PACE center services unless it is fiscally sound as defined in §460.80(a) and has demonstrated competence with the PACE model as evidenced by successful monitoring by CMS and the SAA.</p>		
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3.15 Required Services

The purpose of this section is to ensure that all PACE applicants provide a benefit package for PACE participants consistent with the requirements of §460.90, §460.92, and §460.96.

A. In HPMS, complete the attestations and applicable uploads below:

<p>RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: REQUIRED SERVICES</p>	<p>YES</p>	<p>NO</p>
<p>1. Applicant agrees to provide a PACE benefit package for all participants, regardless of the source of payment as specified in §460.92(a), 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 approved Medicaid state plan; and • Other services that the IDT determines are necessary to improve and maintain the participant's overall health status. 		
<p>2. Applicant agrees that decisions by the interdisciplinary team to provide or deny services must be based on an evaluation of the participant that takes into account (§460.92(b)):</p> <p>(1) The participant’s current medical, physical, emotional, and social needs; and</p> <p>(2) Current clinical practice guidelines and professional standards of care applicable to the particular service.</p>		
<p>3. Applicant agrees to provide a PACE benefit package for all participants, regardless of the source of payment as specified in §460.96, that excludes the following:</p> <ul style="list-style-type: none"> • 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 approved Medicaid state plan). 		

<p>4. Applicant agrees to provide a benefit package in which Medicare and Medicaid benefit limitations and conditions relating to amount, duration, scope of services, deductibles, copayments, coinsurance, or other cost sharing do not apply, per §460.90(a).</p>		
<p>5. Applicant agrees that the participant, while enrolled in the PACE program, must receive Medicare and Medicaid benefits solely through the PACE organization, per §460.90(b).</p>		

3.16 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 attestations and applicable uploads below:

<p>RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: SERVICE DELIVERY</p>	<p>YES</p>	<p>NO</p>
<p>1. Applicant agrees to be responsible for providing care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year, and must establish and implement a written plan to ensure that care is appropriately furnished, per §460.98(a).</p>		
<p>2. Applicant agrees to provide and oversee the provision of services as specified in §460.98(b):</p> <ul style="list-style-type: none"> • Including furnishing comprehensive medical, health, and social services that integrate acute and long-term care; and • Delivered in at least 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 and • Document, track and monitor the provision of services across all care settings in order to ensure the interdisciplinary team remains alert to the participant’s medical, physical, emotional, and social needs regardless of whether services are formally incorporated into the participant's plan of care. 		

RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: SERVICE DELIVERY	YES	NO
<p>3. Applicant agrees to arrange and schedule IDT approved services within the timeframes required at 460.98(c).</p> <p>Applicant agrees to provide all IDT approved services as expeditiously as the participant’s health condition requires, taking into account the participant’s medical, physical, emotional, and social needs.</p>		
<p>4. Applicant agrees, at a minimum, to provide the following services at each PACE center as specified in §460.98(d):</p> <ul style="list-style-type: none"> • Primary care, including services furnished by a primary care provider as defined in §460.102(c) 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>5. 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 §460.98(e) and §460.98(f):</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>6. Applicant agrees to provide each participant primary medical care delivered by a PACE primary care provider as specified in §460.102(c)(1), and §460.102(c)(2) 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. 		

3.17 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 attestations and applicable uploads below:

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

3.18 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 attestations and applicable uploads 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 §460.102(a).</p>		
<p>2. Applicant ensures that the IDT is composed of at least a Primary care provider, 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 or representative, Driver or representative as specified in §460.102(b).</p> <p>Note: One individual may fill two separate roles on the interdisciplinary team where the individual meets applicable state licensure requirements and is qualified to fill the two roles and able to provide appropriate care to meet the needs of participants.</p>		
<p>3. Applicant ensures that primary medical care is provided by a PACE primary care provider as defined in §460.102(c)(1) who is responsible for the following as specified in §460.102(c)(2):</p> <ul style="list-style-type: none"> • Managing participant medical situations; and • Overseeing the participant use of medical specialists and inpatient care. 		

<p>RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: INTERDISCIPLINARY TEAM</p>	<p>YES</p>	<p>NO</p>
<p>4. Applicant ensures that the IDT and individual IDT members do the following as specified in §460.102(d):</p> <ul style="list-style-type: none"> • Completes initial assessments, periodic reassessments, and plans of care; • Coordinates 24-hour care delivery that meets participant needs across all care settings, including but not limited to: • Ordering, approving, or authorizing all necessary care. • Communicating all necessary care and relevant instructions for care. • Ensuring care is implemented as it was ordered, approved, or authorized by the IDT. • Monitoring and evaluating the participant’s condition to ensure that the care provided is effective and meets the participant’s needs. • Promptly modifying care when the IDT determines the participant’s needs are not met in order to provide safe, appropriate, and effective care to the participant. • Document all recommendations for care or services and the reason(s) for not approving or providing recommended care or services, if applicable, in accordance with §460.210(b). • Review, assess, and act on recommendations from emergency or urgent care providers, employees, and contractors within the timeframes required in §460.102(d)(iv) (A) and (B). • Ensure IDT-approved recommended services are arranged, scheduled, and provided in accordance with 460.98(c) timeframes. • Regularly inform the IDT of the medical, functional, and psychosocial condition of each participant; • Remain alert to pertinent input from any individual with direct knowledge of or contact with the participant, including the following: (A) Other team members; (B) Participants; (C) Caregivers; (D) Employees; (E) Contractors; (F) Specialists; (G) Designated representatives; and • Document changes of participant's condition in the medical record consistent with documentation policies established by the medical director. 		
<p>5. Applicant agrees to establish written policies and implement procedures to safeguard the privacy of any information that identifies a particular participant consistent with the requirements for confidentiality per §460.200(e).</p>		

3.19 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 attestations and applicable uploads below:

RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: PARTICIPANT ASSESSMENT	YES	NO
<p>1. Applicant ensures that initial participant assessments are comprehensive, in person, and include, at a minimum (§460.104(a)(4)):</p> <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. 		
<p>2. Applicant ensures that each participant receives an initial face-to-face assessment conducted by the following IDT members and completes the assessment in a timely manner in order to meet the requirements in §460.104(b):</p> <ul style="list-style-type: none"> • Primary care provider; • Registered nurse; • Master's level social worker; • Physical therapist; • Occupational therapist; • Recreation therapist or activity coordinator; • Dietitian; • Home care coordinator; and • Other professional disciplines, as recommended by the IDT. <p>(See §460.104(a)(1), §460.104(a)(2) and §460.104(a)(3))</p>		

3. Applicant ensures that IDT members conducting the initial assessments promptly consolidate, within 30 days of the date of enrollment, discipline-specific assessments into a single plan of care for each participant (§460.104(b)).		
RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: PARTICIPANT ASSESSMENT	YES	NO
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 (§460.104(c)): <ul style="list-style-type: none"> • Primary care provider; • Registered nurse; • Master's level social worker; and • Other team members that the primary care provider, registered nurse and Master's-level social worker determine are actively involved in the development or implementation of the participant's plan of care. 		
5. Applicant ensures that IDT members conducting reassessments promptly complete the following (§460.104(e) and (f)): <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. 		
6. Applicant ensures that the IDT conducts unscheduled reassessments per requirements at §460.104(d): <ul style="list-style-type: none"> • Changes in participant health or status or psychosocial status; or <ul style="list-style-type: none"> • In response to a service determination request the PACE organization expects to deny or partially deny, in accordance with §460.121(h). 		
7. Applicant ensures that semi-annual reassessments are conducted face-to-face by the applicable IDT members specified in §460.104(c).		

3.20 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 attestations and applicable uploads below:

RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: PLAN OF CARE	YES	NO
<p>1. Applicant ensures interdisciplinary team members specified in § 460.102(b) will develop, evaluate, and if necessary, revise a comprehensive person-centered plans of care for each participant that take into consideration the most current assessment findings and identify the services to be furnished to attain or maintain the participant’s highest practicable level of well-being.</p>		
<p>2. Applicant ensures that timeframes required under §460.106(b) for developing, evaluating, and revising plan of care will be followed, including:</p> <ul style="list-style-type: none"> • Initial plan of care. The interdisciplinary team must complete the initial plan of care within 30 calendar days of the participant’s date of enrollment. • Semi-annual plan of care evaluation. At least once every 180 calendar days from the date the latest plan of care was finalized the interdisciplinary team must complete a reevaluation of, and if necessary, revisions to each participant’s plan of care. • Change in participants status. Re-evaluation of, and if necessary, revisions to a participant’s plan of care within 14 calendar days after the PACE organization determines, or should have determined, that there has been a change in the participant’s health or psychosocial status, or more expeditiously if the participant’s condition requires. If a participant is hospitalized within 14 calendar days of the change in participant status, the interdisciplinary team must complete a reevaluation of, and if necessary, revisions to the plan of care as expeditiously as the participant’s condition requires but no later than 14 calendar days after the date of discharge from the hospital. 		
<p>3. Applicant ensures that each plan of care satisfies all requirements per §460.106(c), including:</p> <ul style="list-style-type: none"> • Identifying all of the participant’s current medical, physical, emotional, and social needs, including all needs associated with chronic diseases, behavioral disorders and psychiatric 		

<p>disorders that require treatment or routine monitoring;</p> <ul style="list-style-type: none"> • Addresses each of the factors in §460.106(c)(1)(i-xiii); • Identifies each intervention needed to meet each medical, physical, emotional, and social need (except for medications if a comprehensive list is documented elsewhere in the medical record), how each will be implemented, including a timeframe for implementation; • Identifies measurable goal for each intervention and how the goal will be evaluated to determine whether the intervention should be continued, discontinued, or modified; • Utilizes the most appropriate interventions for each care need that advances the participant toward a measurable goal and outcome; and • The participant’s preferences and goals of care. 		
<p>4. Applicant ensures that the IDT members implement, coordinate and monitor delivery of all services (direct and contracted and in all settings) prescribed in the care plan §460.106(d).</p>		
<p>5. Applicant ensures that the IDT will evaluate and monitor the participant’s medical, physical, emotional, and social needs as well as the effectiveness of the plan of care, through the provision of services, informal observation, input from participants or caregivers, and communications among members of the interdisciplinary team and other employees or contractors.</p>		
<p>6. Applicant ensures that the IDT will involve the participant and/or caregiver or both in development of plan of care §460.106(e), including:</p> <ul style="list-style-type: none"> • Develop, evaluate, and revise each plan of care in collaboration with the participant, the participant’s caregiver, or both. • Review and discuss each plan of care with the participant or the participant’s caregiver or both before the plan of care is completed to ensure that there is agreement with the plan of care and that the participant’s concerns are addressed. 		
<p>7. Applicant ensures that the IDT provides documentation in the medical record for the following:</p> <ul style="list-style-type: none"> • 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. 		

3.21 Restraints

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

A. In HPMS, complete the attestations and applicable uploads below:

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: RESTRAINTS	YES	NO
<p>1. Applicant agrees to use the least restrictive and most effective restraint available.</p> <p>Note: A restraint may be chemical or physical and is defined in the regulation at §460.114(a).</p>		
<p>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.</p>		
<p>3. Applicant ensures that restraints are used for a defined, limited period of time based upon the assessed 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.</p>		
<p>4. Applicant ensures that the condition of the restrained participant is continually assessed, monitored, and reevaluated.</p>		

3.22 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 attestations and applicable uploads 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 §460.72(b).		

3.23 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 §460.84, and §460.100.

A. In HPMS, complete the attestations and applicable uploads below:

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: EMERGENCY AND DISASTER PREPAREDNESS	YES	NO
1. Applicant agrees to comply with all applicable federal, state and local emergency preparedness requirements. This includes establishing and maintaining an emergency preparedness program that meets all requirements as specified in §460.84.		
2. Applicant ensures that the emergency plan holds harmless CMS, the state, and the PACE participant if the PACE organization does not pay for emergency services as specified in §460.100(a).		
3. Applicant agrees to provide for emergency services, both inpatient and outpatient settings, by a qualified emergency services provider, other than the PACE organization, or one of its contract providers, either in or out of the PACE organization's service area, in order to evaluate or stabilize an emergency medical condition as specified in §460.100(b).		
4. 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 §460.100(d).		
5. Applicant agrees to provide access to on-call providers 24-hours a day to consult about emergency services as specified in §460.100(e)(1).		
6. Applicant agrees to provide authorization of urgently needed out-of-network services and post-stabilization care services following emergency services and provide coverage when services are pre-approved by the PACE organization, the PACE organization cannot be contacted, or the PACE organization did not respond to a request for approval within 1 hour after being contacted as specified in §460.100(e).		

3.24 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 attestations and applicable uploads 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 (§460.76(a)).		
2. Applicant agrees to maintain the transportation vehicles it owns, rents, or leases in accordance with the manufacturer's recommendations (§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 (§460.76(b)(2)).		
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 (§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 (§460.76(d)).		
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 (§460.76(e)).		
7. (SAE only) Applicant agrees that the transportation system has been considered and modified, as necessary, to accommodate the proposed service area/site expansion.		

3.25 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 attestations and applicable uploads 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 (§460.78(a)).		
2. Applicant ensures that each meal will meet the following requirements consistent with the requirements of §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 (§460.76(a)(2)).		
4. Applicant agrees to provide nutritional support based on participant condition or diagnosis which include: <ul style="list-style-type: none"> • Tube feedings; • Total parenteral nutrition; and • Peripheral parenteral nutrition. (§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.		

3.26 Termination

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 attestations and applicable uploads 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 §460.50(d): <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 §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 §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 provide assistance to each participant in obtaining necessary transitional care through appropriate referrals and supply new providers the participant's medical records, during the process of terminating the PACE program agreement as specified in §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.

3.27 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 attestations and applicable uploads below:

<p>RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: MAINTENANCE OF RECORDS & REPORTING DATA</p>	<p>YES</p>	<p>NO</p>
<p>1. Applicant ensures data collection, record maintenance, and report submission as required by CMS and the SAA per §460.200(a). Note: Reports include those necessary for CMS and the state to monitor the operation, cost, quality, effectiveness of the program, and establish payment rates.</p>		
<p>2. Applicant ensures CMS and SAA access to data and records per §460.200(b) including, but not limited to:</p> <ul style="list-style-type: none"> • Participant health outcomes data; • Financial books and records; • Medical records; and • Personnel records. 		
<p>3. Applicant ensures CMS and the SAA are able to obtain, examine or retrieve participant health outcomes data, which may include reviewing information at the PACE site or remotely, and agrees that this may entail uploading or electronically transmitting information, or sending hard copies of required information by mail, per §460.200(b)(2).</p>		
<p>4. Applicant ensures written policies and implementation of procedures to safeguard data, books and records against the following as specified in §460.200(d)(1):</p> <ul style="list-style-type: none"> • Loss; • Destruction; • Unauthorized use; and • Inappropriate alteration. 		
<p>5. Applicant ensures confidentiality of health information, per §460.200(e), through policies and procedures that do the following:</p> <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. 		

<p>6. Applicant ensures retention of records, per §460.200(f), for the longest of the following periods:</p> <ul style="list-style-type: none"> • Time specified in State law; • Ten (10) years from the last entry date in the record or for medical records of disenrolled participants, ten (10) years after the date of disenrollment; or • Completion of litigation or associated resolution of claims, financial management review or audit, if started before the expiration of the retention period. 		
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3.28 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 attestations and applicable uploads below:

<p>RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: MEDICAL RECORDS</p>	<p>YES</p>	<p>NO</p>
<p>1. Applicant agrees to maintain a single, comprehensive medical record for each participant, in accordance with accepted professional standards, as specified in §460.210(a).</p>		
<p>2. Applicant ensures that the health information management policy has procedures that govern the maintenance of a single comprehensive medical record for each participant that is (§460.210(a)(2)):</p> <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. 		
<p>3. Applicant ensures that the medical record contains, at a minimum, all required components specified in §460.210(b).</p>		
<p>4. Applicant agrees to promptly transfer copies of pertinent medical record information between treatment facilities, per §460.210(c).</p>		

<p>5. Applicant's medical records are appropriately authenticated, per §460.210(d), by ensuring the following:</p> <ul style="list-style-type: none"> • All entries are 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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3.29 Quality Improvement Program

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 quality improvement program in accordance with 42 CFR §460, Subpart H, §460.200, and §460.202.

A. In HPMS, complete the attestations and applicable uploads below:

<p>RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: QUALITY IMPROVEMENT PROGRAM</p>	<p>YES</p>	<p>NO</p>
<p>1. Applicant agrees to do the following as specified in §460.130:</p> <ul style="list-style-type: none"> • Develop, implement, maintain and evaluate an effective, data-driven quality improvement program; • Reflect the full range of services furnished by the PACE organization; and • Take action resulting in improvements in its performance in all types of care; and • Meet external quality assessment and reporting requirements, as specified by CMS or the SAA, in accordance with §460.202. 		

<p>RESPOND ‘YES’ OR ‘NO’ TO EACH OF THE FOLLOWING STATEMENTS: QUALITY IMPROVEMENT PROGRAM</p>	<p>YES</p>	<p>NO</p>
<p>2. Applicant agrees to use data collected through the health information system to identify areas for improvement in the delivery of services, quality, and safety across care domains (PACE center, home, inpatient, outpatient, rehabilitative etc.) as specified in §460.136 by doing the following:</p> <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 quality improvement coordinator will do the following as specified in §460.136:</p> <ul style="list-style-type: none"> • Coordinate and oversee implementation of the quality improvement activities; and • Encourage PACE participants and caregivers to participate in quality improvement 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 quality improvement activities and are aware of the results of these activities as specified in §460.136.</p>		
<p>5. Applicant agrees to have one or more committees with community input to do the following as specified in §460.138:</p> <ul style="list-style-type: none"> • Evaluate outcome data measuring quality performance; • Address the implementation of the quality improvement 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. 		

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: QUALITY IMPROVEMENT PROGRAM	YES	NO
6. Applicant agrees to submit, upon request from CMS and/or SAA, data to monitor its operations, costs, quality, and effectiveness of care and to establish payment rates, specified in §460.200(c).		
7. Applicant ensures a health information system to collect, analyze, integrate, and report data to measure the organization's performance as specified in §460.202.		
8. Applicant agrees to submit data and information pertaining to its provision of participant care in the manner, and at the time intervals, specified by CMS and the SAA as specified in §460.202.		
9. Applicant ensures a written quality improvement plan as specified in §460.132.		

B. In the Documents Section, upload a copy of the applicant’s quality improvement plan. Service area expansion applicants are to upload a current description of their quality improvement program.

Note: The quality improvement plan must be developed in accordance with 42 CFR §460.132. A quality improvement program must be developed in accordance with 42 CFR §460.134, including requirements in 42 CFR §460.120(f) and 42 CFR §460.122(i).

3.30 State Attestations

The purpose of this section is to ensure that the state is willing to enter into a PACE program agreement with the applying entity, or, as applicable, is willing to amend the program agreement with a PACE organization applying to expand its service area and/or add a PACE center site, and that it has processes in place to ensure compliance with its obligations under the program at 42 CFR §460.12(b).

A. In HPMS, complete the attestations and applicable uploads below:

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: STATE ATTESTATIONS	YES	NO
1. (Initial Applicants): 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 PACE organization and is willing to enter into a PACE program agreement with the entity.		
1. (SAE Applicants): 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 expand its PACE program and is willing to amend its existing 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 a PACE program agreement.

Note: The document should include the written name and title of the official and the name of the state agency, and the date the document is signed should be within the quarter in which the application is submitted.

- C. In the Documents Section upload the state’s CMS-approved Medicaid capitation payment amount, or the methodology used to calculate the amount, as described in 42 CFR §460.182(b).

Note: If more than one capitation payment is applicable, please identify by cohort. If using the rate methodology, it must be consistent with the methodology included in the approved Medicaid state plan.

- D. In the Documents Section upload a description of the state's 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).

- E. In the documents section upload a description of the state’s process for enrollment of participants into the state system, per §460.182(d), including the criteria for deemed continued eligibility for PACE in accordance with 460.160(b)(3). If the state opts to permit permanent waiver of the annual recertification requirement for nursing home level of care based on a determination 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, include in this document in accordance with 460.160(b)(1).

- F. In the documents section upload the SAA’s criteria for determining if a potential

PACE enrollee is safe to live in the community at the time of enrollment and a description of the state’s process to oversee the applicant’s administration of the criteria, per §460.150(c) and §460.152(b).

G. In the documents section, upload a description of any information provided by the state to participants, to include information on how beneficiaries access the State Fair Hearings process.

H. In the documents section upload a description of the state’s process for disenrollment of participants from the state’s system, per §460.182(d), as well as the process for prior review of involuntary disenrollments in accordance with §460.164(f).

Note: Disenrollment dates must be in accordance with §460.162(a) and §460.164(a).

3.31 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 attestations and applicable uploads 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.			

B. If you are submitting a waiver request in conjunction 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; if applicable, process(es), policies and procedures that will be followed to ensure participant care is not compromised; and a State letter indicating the State's concurrence, concerns and conditions related to the waiver request. Please note that the waiver request is reviewed separately from the application process itself.

3.32 Application Attestation

Applicants are required to upload a completed and signed attestation certifying that all information and statements made in the application are true, complete, and current to the best of their knowledge and belief and are made in good faith.

A. Please upload your application attestation document.

3.33 State Readiness Review

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

A. Please upload your State Readiness Review. Note: The State Readiness Review upload is required for initial PACE applications and SAE applications that include a new PACE center. The State Readiness Review may be submitted in response to a request for additional information if not available at the time of application submission. If applying for an SAE with no new PACE Center, the upload is not required.

4 Document Upload Templates

4.1 Governing Body

GOVERNING BODY

NAMES AND CONTACT LIST

[Appendix A of Program Agreement]

(Instruction: Per requirements at 42 CFR §460.62, provide the names and contact information for members of the Governing Body in the format below. Please note which member(s) serves as the participant representative.)

1. Name of Program Director:

Telephone Number:

E-mail address:

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

Telephone Number:

E-mail address:

3. Governing Body members/Board of Directors:

* Serves as participant representative

4.2 Legal Entity and Organizational Structure

LEGAL ENTITY AND ORGANIZATIONAL STRUCTURE

[Appendix B of Program Agreement]

(Instruction: Describe the organizational structure of the PACE organization, consistent with the requirements at 42 CFR §460.60, including the relationship to, at a minimum, the governing body, program director, medical director, and to any parent, affiliate, or subsidiary entity.)

4.3 Subordinated/Guaranteed Debt

If the applicant has a subordinated/guaranteed debt arrangement, the applicant must complete the “Subordinated/Guaranteed Debt Attestation” 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 3.4.1).

4.4 Explanation of Rights

EXPLANATION OF RIGHTS

[Appendix D of Program Agreement]

(Instruction: Include a description of the Participant Bill of Rights. This must be consistent with the requirements at 42 CFR §460.110, §460.112, §460.116, and §460.118. Refer to the PACE Participant Rights template document, which includes current requirements, at: <https://www.cms.gov/Medicare/Health-Plans/PACE/Overview>.)

4.5 Enrollment

ENROLLMENT

[Appendix E of Program Agreement]

(Instruction: Describe policies and procedures for eligibility and enrollment, including the state's criteria used to determine if individuals are able to live in a community setting without jeopardizing their health or safety. Note: The policies and procedures for eligibility and enrollment must be developed in accordance with 42 CFR §460.150, §460.152, §460.154, §460.156, §460.158, and §460.160.)

4.6 Additional Enrollment Criteria

ADDITIONAL ENROLLMENT CRITERIA

[Appendix F of Program Agreement]

(Instruction: Describe any additional enrollment criteria. Note: The criteria must be developed in accordance with 42 CFR §460.150(b)(4). If not applicable, please state N/A.)

4.7 Voluntary Disenrollment

VOLUNTARY DISENROLLMENT

[Appendix G of Program Agreement]

(Instructions: Describe voluntary disenrollment policies and procedures. Note: This process must be developed in accordance with 42 CFR §460.162, §460.166, §460.168, §460.170, and §460.172.)

4.8 Involuntary Disenrollment

INVOLUNTARY DISENROLLMENT

[Appendix H of the Program Agreement]

(Instructions: Describe involuntary disenrollment policies and procedures. Note: This process must be developed in accordance with 42 CFR §460.164, §460.166, §460.168, §460.170, and §460.172.)

4.9 Grievances

GRIEVANCES

[Appendix I of Program Agreement]

(Instructions: Describe policy and procedure for grievances. Note: This process must be developed in accordance with 42 CFR §460.120 and should specify whether the timeframes for responding to grievances are calendar days or business days.)

4.10 Appeals

APPEALS AND ADDITIONAL APPEAL RIGHTS

[Appendix J of Program Agreement]

(Instructions: Describe the policy and procedure for the appeals process. Describe policies and procedures regarding participants' additional appeals rights under Medicare and/or Medicaid. Note: The PO's appeals process must be developed in accordance with 42 CFR §460.122 and should specify whether the timeframes referenced are for calendar days or business days. The external appeals process must be developed in accordance with 42 CFR §460.124, including the process for filing any further appeals, and should specify whether the

timeframes for responding to appeals are calendar days or business days.)

4.11 Quality Improvement Program

QUALITY IMPROVEMENT PROGRAM

[Appendix K of Program Agreement]

(Instructions: Initial PACE applicants must provide a detailed description of the quality improvement plan. Note: The quality improvement plan must be developed in accordance with 42 CFR §460.132. Service area expansion applicants should provide documentation that reflects their quality improvement program consistent with requirements at 42 CFR §460.134, including requirements in 42 CFR §460.120(f) and 42 CFR §460.122(i).)

4.12 Medicare and State Medicaid Capitation Payment

MEDICARE AND STATE MEDICAID CAPITATION PAYMENT

[Appendix M of Program Agreement]

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

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.

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-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. Payments for eligible enrollees of either PBP will also include a low-income premium subsidy and a low-income cost-sharing subsidy for basic Part D benefits. With a few exceptions, Part D payments are made to POs in the same manner as to MA-PD and standalone PDP plans.

The dual eligible plan differs from the defined standard plan in that there is a nominal cost-sharing amount in the defined standard benefit that low-income

beneficiaries pay themselves for each prescription drug event. Because POs cannot apply cost sharing, the dual eligible PACE plan pays this nominal amount, estimated to be 2 percent, and the government in turn reimburses the PACE organizations. Therefore, payments for dually eligible enrollees will also include an additional amount to cover nominal cost sharing amounts (“2% capitation”).

Dual eligible PACE participants are not responsible for Part D premium payments and receive 100 percent premium assistance for the portion of the basic premium below the low-income benchmark. Therefore, there is an additional premium payment to dual eligible plans in situations where the PO’s basic Part D beneficiary premium is greater than the regional low-income premium subsidy amount.

[Insert CMS approved state Medicaid PACE rates into chart, or insert the methodology used to calculate the rates. The methodology must be consistent with the methodology in the approved Medicaid state plan.]

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

4.13 State Enrollment/Disenrollment Reconciliation Methodology

**STATE ENROLLMENT/DISENROLLMENT RECONCILIATION
METHODOLOGY**

[Appendix N of Program Agreement]

(Instructions: Provide a description of the state's 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).)

4.14 Termination

TERMINATION

[Appendix O of Program Agreement]

(Instruction: Provide a detailed termination plan. Note: The plan for termination must be developed in accordance with 42 CFR §460.50 and §460.52.)

4.15 SAA Enrollment Process

SAA ENROLLMENT PROCESS

[Appendix P of Program Agreement]

(Instructions: Provide description of the state’s process for enrollment of participants into the state system in accordance with 42 CFR §460.182(d), as well as the criteria for deemed continued eligibility for PACE in accordance with 42 CFR §460.160(b)(3). If the state opts

to permit permanent waiver of the annual recertification requirement for nursing home level of care, provide information in accordance with §460.160(b)(1).)

4.16 SAA Oversight of PO Administration of Safety Criteria

SAA OVERSIGHT OF PO ADMINISTRATION OF SAFETY CRITERIA

[Appendix Q of Program Agreement]

(Instructions: Provide a description of the state’s process to oversee the applicant’s administration of the criteria for determining if a potential PACE enrollee is safe to live in the community at the time of enrollment, and any associated enrollment denials based on application of that criteria. Note: The process must be developed in accordance with 42 CFR §460.150(c) and 42 CFR §460.152(b).)

4.17 Information Provided by State to Participants

INFORMATION PROVIDED BY STATE TO PARTICIPANTS

[Appendix R of Program Agreement]

(Instructions: Provide a description of any information provided by the state to participants, to include information on how beneficiaries access the State Fair Hearings process.)

4.18 State Disenrollment Process

STATE DISENROLLMENT PROCESS

[Appendix S of Program Agreement]

(Instructions: Provide a description of the state’s process for disenrollment of participants from the state’s system in accordance with 42 CFR §460.182(d), as well as the process for prior review of involuntary disenrollments in accordance with 42 CFR §460.164(f).)

4.19 State Attestations/Assurances Signature Pages

STATE ATTESTATIONS/ASSURANCES SIGNATURE PAGES

[Template for State Attestations/Assurances Document]

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 (SAA). Any application submitted that does not include this signed document will be deemed incomplete and will not be reviewed.

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.

PACE center address for this application: _____
(enter N/A if an expansion application without a new PACE center)

Service area specific to this application. (Include name of each applicable county and specify either full or partial for each. If partial, list all applicable zip codes specific to each county. For expansion applications, only enter the new service area being added. Enter N/A if an expansion application that does not include new service area.)

For a geographic service area expansion application, state agrees that the existing PACE center site(s) is adequate to serve PACE participants who reside in the proposed geographic service area.

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 Medicaid state 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, participants will be evaluated to determine if the participant continues to need the level of care required under the Medicaid state plan for coverage of nursing facility services. (42 CFR §460.160(b))

State may agree to establish a process to 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 until 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.

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

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.

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 at the time of enrollment.

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

State agrees that before an involuntary disenrollment is effective, the SAA will review documentation and determine in a timely manner that the applicant has adequately documented acceptable grounds for disenrollment. (42 CFR §460.164(f))

State agrees to establish a process to receive participant disenrollment information for purposes of coordinating the disenrollment date between Medicare and Medicaid. (42 CFR §460.166)

State agrees 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 enrolled 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 Part 460 Subpart K))

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 §460.94, including details on when and how Medicaid share of cost requirements are imposed.

State certifies that the SAA 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

4.20 Applicant Attestation

CENTERS FOR MEDICARE AND MEDICAID SERVICES CENTER FOR MEDICARE CENTER FOR MEDICAID AND CHIP SERVICES 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 S 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

READINESS REVIEW REPORT

PACE ORGANIZATION:

H #:

DATE (S) OF REVIEW:

REVIEWER (S) – NAME, TITLE, AND DEPARTMENT:

DATE OF COMPLETION:

STATE ADMINISTERING AGENCY:

SAA REPRESENTATIVE SIGNATURE:

STATE READINESS REVIEW

CMS will only approve applications from potential PACE organizations that satisfy federal requirements as determined based on review of the PACE application, and have met the requirements of a State Readiness Review (SRR). The SRR is performed by the state at the applicant's PACE center. 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 based on state specific requirements or 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 appropriate staffing and established contracts necessary to provide all-inclusive, quality care to its participants.

The SRR includes but is not limited to: A review of policies and procedures; the design and construction of the PACE center; emergency preparedness; the site's compliance with OSHA, FDA, state and local laws, and adherence to Life Safety Code requirements. 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.

The state is required to complete a readiness review for new PACE organizations as well as existing PACE organizations that propose to expand by adding a new PACE center site.

Upon completion of the SRR, the state will be responsible for preparing and submitting a completed SRR report ensuring that all required areas are met.

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
PHYSICAL ENVIRONMENT (§460.72)			
<p>I.A. The PACE center must be designed, constructed, equipped, and maintained to provide for the physical safety of participants, personnel, and visitors.</p>	<p>EVIDENCE OF COMPLIANCE WITH ALL STATE AND LOCAL BUILDING, FIRE SAFETY AND HEALTH CODES.</p> <p>Visible 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, hallways 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 non-ambulatory and handicapped participants, staff and visitors; 	<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"> • 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.) and evidence the safeguards are operational. <p>Written plan that outlines scheduled maintenance for the PACE center to include building maintenance.</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"/> 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. Note: If the PACE center is licensed as an adult day center by the state, skip to 1.C.</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.; • Lighting and sound levels in care areas, activity and dining rooms that are appropriate for individuals with vision, hearing, and cognitive impairments; • Proper ventilation; • Written policies and procedures for an effective pest control program to control infestations by pests and rodents not limited to roaches, ants, flies, and mice; • If applicable, 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 <input type="checkbox"/> NOT MET <input type="checkbox"/> N.A.</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 regarding smoking policies, including how to determine if or when participants may smoke with or without supervision (if applicable). • Written policies and procedures on the proper storage, handling, and disposal of all chemicals, compounds and biohazardous 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"/> 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
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>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, and the projected attendance by participants)</p> <ul style="list-style-type: none"> • Team meetings • Medical treatment and other care • Therapeutic recreation • Restorative therapies • Socialization • Personal care • Dining <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>	<input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> MET <input type="checkbox"/> NOT MET	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	<p>Evidence that all storage areas, including food storage, include appropriate clearance from floors, ceilings and other structural elements.</p> <p>OTHER (SPECIFY)</p>	<input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> Other (Specify and Attach)	
<p>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</p>	<p>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.</p> <p>A written plan and monitoring program to check all contracts related to maintenance agreements.</p> <p>Written policies and procedures to ensure compliance with and report device related death and serious injuries to the FDA and/or the manufacturer of the equipment in accordance with the</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
and keep all equipment (mechanical, electrical, and patient care) free of defect. This includes any equipment in the patient's home.	<p>Safe Medical Devices Act of 1990.</p> <p>Evidence of manufacturer's manuals for all equipment (mechanical, electrical, safety/emergency preparedness and patient care).</p> <p>OTHER (SPECIFY)</p>	<input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> Other (Specify and Attach)	
I.E. The PACE center must meet the occupancy provisions of the 2000 edition of the LSC for the type of setting in which it is located	<p>EVIDENCE OF COMPLIANCE WITH THE CURRENT EDITION OF THE LIFE SAFETY CODE or state code that CMS determined adequately protects participants and staff.</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 specific to the PACE center Fire evacuation Plans specific to the PACE center Fire Procedures specific to the PACE center</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"/> Other (Specify and Attach)	

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

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

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
INFECTION CONTROL (§460.74)			
<p>II. At a minimum, the PACE center must have an infection control plan that includes:</p> <p>A. Procedures to identify, investigate, control, and prevent infections in the PACE 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</p>	<p>Written policies and procedures for the investigation, control, and prevention of infections including:</p> <ul style="list-style-type: none"> • A written OSHA Exposure Control Plan which includes the Universal Precautions and Bloodborne Pathogen exposure procedures for staff; • Vaccinating participants and staff against diseases of particular concern for the PACE participant and the PACE center’s geographic location, i.e. influenza and pneumonia (are required minimally); • 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. • Written policies and procedures for the investigation, evaluation, resolution, and reporting of all incidences of staff and participant infection. • Written policies and procedures for maintaining records of staff and participant infections to include post-exposure evaluation, training records, and participant and staff surveillance reports. 	<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
develop corrective actions related to the reduction of future incidents.	<ul style="list-style-type: none"> • Written policies and procedures for reporting required communicable diseases to the appropriate federal, state, and local officials. • Policies and procedures for staff providing direct care to patients with infection(s); • Provision of adequate facilities and supplies necessary for infection control to include: • Hand washing facilities and supplies; • Laundry facilities and supplies if conducted at PACE center; • Isolation facilities and supplies • Written policies and procedures for addressing how laundry will be handled. If the service is contracted out, written agreements to comply with the requirements. • Written policies and procedures for the ongoing monitoring of the contractual agreement provisions for laundry and waste disposal. 	<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 <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"/> NA 	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	<ul style="list-style-type: none"> Written policies 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>OTHER (SPECIFY)</p>	<input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> Other (Specify and Attach)	
Transportation Services (§460.76)			
III. The PACE organization should take appropriate steps to ensure that participants can be safely transported from their homes to the PACE center and to appointments. A. Requirements for the organization's transportation program include: 1. Maintenance of transportation vehicles according to the	<p>Evidence of appropriate state vehicle inspections.</p> <p>If commercial vehicles (greater than 12 seats, usually) are being used, a commercial license is required by all drivers.</p> <p>If the service is contracted out, written agreements to comply with the contract requirements under §460.70.</p> <p>Written policies 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>	<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"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> NA <input type="checkbox"/> MET <input type="checkbox"/> NOT MET	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
<p>manufacturer's recommendations.</p> <p>2. Transportation vehicles equipped to communicate with the PACE center.</p> <p>3. Training transportation personnel on the special needs of participants and appropriate emergency responses.</p> <p>4. As a part of the interdisciplinary process, communicating relevant changes in the participant's care plans to transportation personnel.</p>	<ul style="list-style-type: none"> • Sufficient staff • Written policies and procedures for the training and monitoring of drivers including: • Proper transfer of non-ambulatory and ambulatory participants; • Proper use of equipment needed to transfer and secure participants; • Emergency procedures during transfer, transport, and arrival of participants. • Ability for communication between the driver and PACE center during transportation activities. • Evidence of written policies and procedures on the maintenance of vehicles utilized in the transport of participants. • Written policies and procedures for communication between the interdisciplinary team and the transport staff regarding the needs of the participants being transported. • Written policies and procedures for monitoring the performance of all drivers. 	<p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p>	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	<ul style="list-style-type: none"> • Written policies and procedures regarding smoking or non-smoking on transportation vehicles, and appropriate signage based on policy. • Written procedures to check or audit for the following information on the drivers: <ul style="list-style-type: none"> • Current driver’s license • Record of any traffic violations or accidents that may constitute a potential hazard for the transport of participants. <p>OTHER (SPECIFY)</p>	<input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> Other (Specify and Attach)	
Dietary Services (\$460.78)			
IV. PACE center is required to provide food that is nourishing, palatable, well-balanced, and meets acceptable safety standards: A. Procure food	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). Written policies and procedures that ensure the safe delivery of food and nutritional supplements including: <ul style="list-style-type: none"> • Safe procurement of food and nutritional supplements; 	<input type="checkbox"/> MET <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	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
<p>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; • Provisions for substitute foods or nutritional supplements; • Safe garbage storage and disposal; • Training of staff in safe food delivery; and • Written policies and procedures for emergency food supplies and emergency nutritional supplements 	<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 <input type="checkbox"/> MET <input type="checkbox"/> NOT MET 	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	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. OTHER:	<input type="checkbox"/> MET <input type="checkbox"/> NOT MET	
Bill of Rights (§460.110)			
V. The PACE organization must have written policies and implement procedures to ensure that the participant, his or her representative, and staff understand their rights.	Written policies and procedures governing the participant Bill of Rights including: <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. Written policies and procedures for distributing the Bill of Rights to the participant and his or her representative upon enrollment and annually. Written policies and procedures to ensure that the participant, his or her representative, and staff understand participant rights. The participant PACE Bill of Rights should be in English and any other principal language of the community and be displayed	<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>in an area frequented by the public. <u>Evidence of compliance with state requirement, if any, for specific criteria of the principal 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"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> OTHER (Specify and Attach)</p>	
Personnel Qualifications (§460.64)			

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
<p>VI. The PACE center must have qualified staff to provide care to its frail elderly participants.</p>	<p>Assurance by the state that contracts for all contractors and contracted personnel are executed by the time the PACE center becomes operational.</p> <p>Written position descriptions for all staff (employees and contractors).</p> <p>Assurance by the state that the required members of the interdisciplinary team (primary care provider, registered nurse, Master's-level social worker, PT, OT, recreational therapist or activities coordinator, dietician, PACE center manager, home care coordinator, and PACE center personal care attendants, drivers) are/will be employees or contractors of the PACE center by the time the PACE center becomes operational.</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 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>	<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"/> Other (Specify and Attach)</p>	
<p>TRAINING AND COMPETENCY (§460.66 AND §460. 71)</p>			

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
<p>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 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</p>	<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; • 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: • Training and demonstrated competency on the transport of non-ambulatory participants for drivers and any other applicable staff; 	<p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p>	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
<p>associated with specific care needs of individual participants.</p>	<ul style="list-style-type: none"> • 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; • 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; 	<p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p>	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	<ul style="list-style-type: none"> • Appropriate and safe techniques in personal hygiene and grooming; • Safe transfer techniques and ambulation; • 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"/> Other (Specify and Attach)	
GENERAL PROVISIONS			
VIII. General provisions	Evidence of all current licensure required in the state: <ul style="list-style-type: none"> <input type="checkbox"/> ADHC <input type="checkbox"/> Home Health <input type="checkbox"/> Clinic <input type="checkbox"/> HMO <input type="checkbox"/> Ambulatory Care Center <input type="checkbox"/> Other - specify 	<input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> N/A	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	<p>Written policies 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 participant representative's request.</p> <p>Verify the PACE organization's actual service area.</p> <p>Verify the process the PACE organization has in place to ensure participant access to care 24 hours a day, 7 days a week.</p> <p>Verify that the PACE organization's network will include all required services (through staff or contract) by the time the PACE Center becomes operational.</p> <p>Evidence of a health information system to collect, analyze, and report participant data.</p> <p>OTHER (SPECIFY)</p>	<p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> Other (Specify and Attach)</p>	
General Safety Requirements			

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
IX. Overall PACE Center safety requirements	<p>Evidence of state pharmacy licensure.</p> <p>Written policies and procedures for narcotic inventory control and disposal.</p> <p>All Medications are locked in a cabinet, room or cart.</p> <p>Written policies and procedures for refrigerator temperature logs used for medication and food storage.</p> <p>Written policies 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>	<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 <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> Other (Specify and Attach)</p>	