

Centers for Medicare and Medicaid Services
Provider Application
Suggested Format

**PROGRAM OF ALL-
INCLUSIVE CARE FOR THE
ELDERLY
(*PACE*)**

Department of Health and Human Services
Centers for Medicare and Medicaid Services
Center for Beneficiary Choices
Center for Medicaid and State Operations

December 2004

PROGRAM OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

INTRODUCTION

PREPARATION OF THE APPLICATION

This computer-assisted format is for IBM compatible personal computers using MS Word 97 or later. Please see the technical instructions included within this application for working on the application. The attached application form is a suggested format for complying with the regulations; other formats will be accepted. However, to assure consistent information from applicants and an efficient review process, you are encouraged to use these forms.

REFERENCE MATERIALS

Information requested in this application is based on Sections 1894 and 1934 of the Social Security Act, as added by P.L. 105-33, and the regulations at 42 CFR Part 460.2 - 460.210.

NOTE: It is the responsibility of the PACE organization and the State Administering Agency to validate the information contained in each application.

GENERAL INSTRUCTIONS

To clarify any question, refer to the regulation upon which it is based. A regulatory citation is provided at each question.

A completed application includes:

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

Number all pages consecutively from the Narrative through the entire Documentation part. Use a page number when referring to any document. If pages must be inserted after numbering has been completed, additional pages may be noted by A, B, C, etc.

TABLES: Within the application, you will be directed to place tables in specific places within the Narrative chapters. For those using the computerized application, placement will be automatic; otherwise, you may insert the tables at the end of each chapter. Include the completed tables as separate files on the diskette you will be submitting..

PRINTING AND BINDING: Both sides of the page should be used. Tabs should be inserted for each chapter of the Narrative and Documents parts. Each copy should be put in three-ring looseleaf binders. A typical application is two three-inch binders.

NUMBER OF COPIES: Send 7 hard copies and 3 diskette copies of your application to the State Administering Agency in addition to the numbers of copies required by the State agency.

ASSISTANCE: Assistance is available to all applicants in the preparation of this application. You may call Ms. Terry Pratt at 410-786-5831 at the Centers for Medicare and Medicaid Services.

TECHNICAL INSTRUCTIONS

Using the computer assisted format, you will need only to fill in responses in the Narrative part and the applicable tables. For the Documents part, you will need to assemble the documents as directed within the application form and General Instructions. The Documents part does not have a computer assisted format.

SYSTEM REQUIREMENTS: An IBM or compatible personal computer with high density floppy drive, and MS Word 97 or later.

The computerized application was designed using a 12-point Times New Roman *proportionally-spaced* font. Other printers may have comparable fonts such as Times Roman, Dutch 801 Roman, Charter, etc., and these fonts should be suitable, but may format pages slightly differently.

INSTALLATION: After downloading the application files, be sure they are all on a separate directory. Save one set of files as the original >blank= forms and a second set of the completed files. As a safeguard, copy the files onto a separate floppy disk so you will have a back-up in the event of a hard disk problem.

COMPLETION OF THE APPLICATION: After installation, the next step is the completion of the application itself on the computer's hard disk within the PACE directory.

The files supplied are MS Word documents: *paceapp.doc*, *paceinsu.doc*; *pacehsd.doc*, and *paceread.doc*, which includes a description of each file.

To insert your responses in the Narrative chapters, simply position the cursor at the appropriate point for answering the question, and type in the answer. The rest of the application will "bump down" as you type, providing you as much space as needed.

Several tables are provided as separate files on the disk and should be filled in at their separate location. These are coded for small print size. (See Table Management below.) The Narrative sections instructs you on where to place hard copies.

Be sure to resave the document frequently as you progress.

TABLE MANAGEMENT: If you need copies of a table, you should create multiple blank tables within the same file, being sure to place a hard page break between each table. You can use the copy and past functions to accomplish this task. Save the entire file, now containing two or more tables, with the original file name.

Repeat this process each time you need multiple tables within a single file.

PAGINATION is completely automatic within the Narrative part, so the user should not attempt to type in page numbers as ordinary text.

A NARRATIVE TABLE OF CONTENTS at the beginning of the application is created or updated every time you generate the Table of Contents. (See instructions below.) You should create or update the Table of Contents as the last step before actually printing the application for submission.

After you have created a Table of Contents within a document, any subsequent editing, no matter how minor, may alter the page numbering in the Table. For that reason, before you print your final version, regenerate a final Table of Contents.

PRINTING THE APPLICATION FOR SUBMISSION:

To generate the Table of Contents for the Narrative part, **place the cursor at the immediate left** of the word 'Chapter 1' on the Narrative Table of Contents page. Then:

click on **Insert** on the menu bar

select **Indexes and Tables...**

click on **Table of Contents** tab – the following should be selected:

check on **show page numbers** and **right align page numbers**

select **Tab leader ...**; select **Format 'from template'** ; **Show levels** should be **2**

click on **OK**; when asked if you want to replace the table of contents, select **yes**

To add the page numbers for the Documents table of contents, place cursor at the end of each line (using the End key) and type in the page number. Do not press enter, just place the cursor at the end of the next line for the next page entry.

Save the end result as XXXXXXXXX.doc, with the Xs being an abbreviated applicant name.

When you are ready to submit your application, copy all completed files from the PACE directory on your hard disk to a blank diskette. Be certain not to further edit any file, either on hard disk or diskette to assure that the printed copy is identical to the diskette copy. Print each file and compile as directed in the narrative.

Submit both the diskette and hard copies as directed in the general instructions. Please clearly label the diskette with the applicant's name, date, and type of application.

GENERAL GUIDELINES FOR SUCCESS: Throughout the application, there are references to documents that are separate files on disk. Most of these files should be printed and placed in the hard copy of the application as directed, usually in a Documents part. However, simply leave the files as individual files on the diskette. Do not integrate the files into the application file on the diskette.

- ! Each file deals with a specific topic only. Don't append material to any file that belongs elsewhere.*
- ! Edit each file under its own file name.*
- ! The files supplied have both visible and invisible Word codes. Don't delete any of these codes. Don't attempt to replace these files with new ones of your own creation (the codes will be lost).*
- ! Pagination is automatic in the Narrative part; do not attempt to insert page numbers as text.*

This procedure is harder to describe than to perform -- it is not as complicated as it may seem!

THE APPLICATION FORM FOLLOWS THIS PAGE

**DO NOT SUBMIT THE PREVIOUS PAGES
IN THE PRINTED COPY OF YOUR APPLICATION**

**CENTERS FOR MEDICARE AND MEDICAID SERVICES
 CENTER FOR BENEFICIARY CHOICES
 CENTER FOR MEDICAID AND STATE OPERATIONS
 PROVIDER APPLICATION
 PROGRAM OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)**

NAME OF LEGAL ENTITY TRADE NAME (if different)	MAILING ADDRESS
AREA CODE TELEPHONE NO. EXTENSION	FAX
CEO OR EXECUTIVE DIRECTOR: NAME AND TITLE TELEPHONE NUMBER	MAILING ADDRESS
APPLICANT CONTACT PERSON: NAME TITLE ADDRESS E-MAIL FAX TELEPHONE NUMBER	

I certify that all information and statements made in this application are true, complete, and current to the best of my knowledge and belief and are made in good faith.

Signature, CEO / Executive Director

Date

FOR USE BY STATE ADMINISTERING AGENCIES

Note: It is the responsibility of the PACE organization and the State Administering Agency (SAA) to validate the information contained in each application. The Director of the State Administering Agency must sign this certificate and submit it to CMS along with the complete PACE Organization application.

I certify that the entity described in this application is qualified to be a PACE provider.

I certify that the State of _____ is willing to enter into a program agreement with the entity described in this application.

I certify that this PACE Organization will have an enrollment limit of _____ participants (if state enrollment limit applies).

Provide a description of the SAA's enrollment process, to include the process for conducting annual level of care recertifications and the criteria for deemed continued eligibility for PACE , in accordance with 42 CFR §460.160 (b).

Provide a description of the SAA's process for overseeing the PACE Organization's administration of the criteria for determining if a potential PACE enrollee is safe to live in the community.

Provide a description of the information to be provided by the SAA to enrollees, to include information on how beneficiaries access the State's Fair Hearings process.

Provide a description of the SAA's disenrollment process.

Describe the methodology the State used to develop the PACE Medicaid capitation rates. A detailed description of how the Upper Payment Limit (UPL) was determined must accompany the Program Application. If rates have been developed as a percentage of the State's UPL, the State must provide assurance that the rates are less than the UPL. If the State has developed rates separately from the UPL, then a detailed description of the elements of that rate development must also accompany the Program Application.

Provide a description of the SAA's 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, in accordance with 42 CFR §460.182(d).

Provide a description of how Medicare benefit requirements are protected for dually eligible PACE participants upon entering a facility, in accordance with section 460.90. Describe when and how Medicaid share of cost requirements are imposed.

FOR NON-OPERATIONAL SITES ONLY

I certify that the SSA 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

NARRATIVE PART TABLE OF CONTENTS

The table of contents for the completed application is placed after the cover sheet.

For computerized application users: each chapter and subsection title within the Narrative part is marked for automatic generation of the table of contents on this page. That table appears below with page numbering that reflects a "blank" application. The numbers will change when you generate the table again for the completed application. Please follow the directions in the Technical Instructions to generate the table for the Narrative Part. Note that the table of contents for the Documents Part is not generated automatically, and is to be manually filled in after the table for the Narrative.

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Participant Consent Form for Release of Information.

*For computerized application users: To add the page numbers for the Documents table of contents, place cursor at the end of each line (using the End key) and type in the page number. Do not press ENTER, just place the cursor at the end of the next line for the next page entry.

Chapter 1 ~ GENERAL INFORMATION & ORGANIZATIONAL

I. SUMMARY DESCRIPTION

Briefly describe the organization in terms of its history and its present operations. Cite significant aspects of its current financial, marketing, general management, and health services delivery activities. (Do not include information requested in the Legal Entity section.) Please include the extent of the current Medicare/Medicaid population served by the applicant, if any, and the maximum number of PACE participants that could be served.

II. SERVICE AREA (§460.22)

Describe the service area the PACE Organization is requesting. The area may be identified by county, zip code, street boundaries, census tract, block or tribal jurisdiction. Provide a detailed map (with a scale) of the complete geographic area clearly showing the boundaries, main traffic arteries, any physical barriers such as mountains and rivers. Show location of the PACE center and hospital providers which will serve PACE participants. Show on map the mean travel time from the farther points on the geographic area boundary to the nearest ambulatory and institutional services sites. Place the map in the Documents part.

III. TRANSITIONAL CARE DURING TERMINATION (§460.52)

Provide the PACE Organization's written plan for phase-down of the PACE program including transitional care for participants. Include all of the elements required in §460.52(a) and (b).

IV. NON-PROFIT STATUS (§460.60)

Supply evidence in the Documents part that the PACE Organization is either an entity of city, county, State or tribal government or a private, not-for-profit entity organized for charitable purposes under Section 501 (c)(3) of the Internal Revenue Code. Place the IRS ruling in the Documents part.

V. ORGANIZED UNDER STATE LAW (§460.60)

Describe how the PACE Organization is organized under State law. If the PACE Organization does business as (d.b.a.) a name or names different from the name shown on its articles of incorporation, provide such name(s) and include a copy of State approval for the d.b.a.(s) in the Documents part.

Provide the name the PACE Organization will use for its PACE Program.

VI. LEGAL ENTITY (§460.60)

Provide a copy of the most recent articles of incorporation, bylaws and other legal entity documentation for the PACE Organization in the Documents part.

VII. ORGANIZATIONAL STRUCTURE (§460.60)

- A. Provide a current organizational chart of the PACE Organization showing officials in the PACE Organization and relationships to any other organizational entities. Place the chart at the end of this chapter.
- B. If the PACE Organization is part of a corporate entity, describe the PACE Organization's relationship to the corporate board and to any parent, affiliate or subsidiary corporate entities.
- C. Provide position descriptions and resumes for the Program Director and Medical Director in the Documents part.
- D. Provide the name and job description for the HIPAA privacy officer

VIII. GOVERNING BODY (§460.62)

- A. Describe the governing body of the PACE Organization and explain how it will provide oversight authority of the following functions:
 - Governance and operation.
 - Management and provision of all services, including the management of subcontractors.
 - Fiscal operations.
 - Personnel policies.
 - Development of policies on participant health and safety.
 - Quality assessment and performance improvement program.
- B. Provide a current list of the members of the Board of Directors. Indicate which, if any, members are consumer representatives.

<u>Name</u>	<u>Title</u>	<u>Representation</u>
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- C. Provide the name and phone number of a contact person for the governing body.

IX. CONSUMER ADVISORY COMMITTEE (§460.62)

Describe the membership and the functions of the Consumer Advisory Committee that provides advice to the governing board on matters of concern to participants.

Provide an assurance that participants or representatives constitute a majority of Committee membership.

Chapter 2 ~ *PACE ADMINISTRATION*

I. TRAINING (§460.66)

- A. Explain the training program of the PACE Organization. [Provide training manuals at the site visit.] Include a detailed description of your plan for performing initial competency and ongoing skills reviews. The description should include the minimum skills necessary to perform the job, how the skills are assessed, and ongoing training plans.
- B. Describe the process for training staff on your HIPAA privacy policies.
- C. Describe the training program for personal care attendants. (Include the same level of detail as above.)

II. PROGRAM INTEGRITY (§460.68)

- A. Indicate the process used to ensure that PACE Organization employees and contractors:
 - 1. Have not been convicted of criminal involvement in Medicaid, Medicare, other health insurance or health care programs, or social service programs under Title XX of the Social Security Act.
 - 2. Have not been excluded from participation in the Medicare or Medicaid programs, or debarred from Federal agencies.
 - 3. Are not employed in any capacity where an individual's contact with participants would pose a potential risk because the individual has been convicted of physical, sexual, drug or alcohol abuse.
- B. How does the PACE Organization assure that no member of the governing body, or any of their immediate family members, have a direct or indirect interest in any contract that supplies any administrative or care-related services or materials to the PACE Organization?

III. CONTRACTED SERVICES (§460.70)

- A. Provide the name of the employee who will serve as the official liaison to coordinate activities between contractors and the PACE Organization.
- B. Provide a copy in the Documents part of the list, kept on file at the PACE Center, of all administrative and care-related contractors.

- C. Provide a copy of a sample contract for all administrative and care-related contracts (including inpatient, Nursing Facility, home care, and specialty care) that is inclusive of HIPAA language.
- D. Describe the oversight process the PACE Organization will use to ensure that contracts and contractors meet PACE Program and Federal requirements, inclusive of being HIPAA compliant.

IV. OVERSIGHT OF DIRECT PARTICIPANT CARE (§460.71)

- A. Describe your process and content for your ongoing competency program, background checks, health screening, and credential verification for all direct care staff (employees, contractors and volunteers).
- B. Provide the name of the employee who will oversee these activities for employees, and will work with the contractor liaison to ensure compliance by contractor staff.

V. PHYSICAL ENVIRONMENT (§460.72)

- A. Describe how the PACE Organization ensures that the PACE Center:
 - 1. Is designed, constructed, equipped and maintained to provide for the physical safety of participants, personnel, and visitors.
 - 2. Will provide a safe, sanitary, functional, accessible, and comfortable environment for the delivery of services that protects the dignity and privacy of the participant.
- B. Describe the PACE organization's plan to ensure that all equipment is maintained in accordance with manufacturers' recommendations. The plan should include the following:
 - Identifying equipment.
 - How manufacturers' recommendations will be met.
 - Maintenance schedules.
 - How FDA injuries are reported (see www.fda.gov for "medical device" definition and reporting requirements)

- C. Describe how the PACE Organization meets the occupancy provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association.

If you are requesting an exception to complying with the Life Safety Code for either of the reasons specified in 460.72 (b)(2), please provide a justification for your request.

- D. Emergency readiness – describe the PACE Organization's plan to:

1. Manage non-medical emergencies and disasters that include either shelter in place or evacuation and transportation procedures, emergency supplies and staffing responsibilities.
 2. Have patient ready (operating and clean) emergency equipment and drugs, and staff that knows how to use them on the PACE Center premises at all times the Center is open. Include how you will verify drugs have not expired, and how emergency medical assistance from outside sources will be obtained.
 3. Manage medical emergencies for events in the Center, during participant transport, in the participant's residence, and after hours (after the Center is closed). This plan must include responding to DNRs/other Advance Directives, choking, stopped breathing or heart cessation.
 4. At least annually, test, evaluate, and document the effectiveness of its emergency and disaster plans.
 5. Provide orientation and periodic training to staff, contractors, and participants on the emergency and disaster plan.
- E. Infection Control (§460.74) – Provide a description of the procedures for the investigation, control, and prevention of staff and participant infections. The description must include how CDC guidelines and OSHA regulations (universal precautions, exposure control plans, vaccinations, health screenings) are met. Include how trends in infections will be analyzed and corrected. For ease in submission, a copy of the table of contents can be attached with the description of the Infection control plan.
- F. Transportation (§460.76) – Provide a description of the PACE Organization's procedures for:
1. Performing preventative and routine maintenance on all participant use vans.
 2. Providing training to all transportation personnel (employees and contractors) that minimally include: managing the special needs of participants, handling emergency situations, communication protocols and grievance and incidence reporting.
 3. Communicating changes in a participant's care plan to transportation personnel.
 4. Ensuring effective communication between the vans and the PACE Centers.

- G. Dietary Services (§460.78) – Describe the PACE Organization’s procedures for:
1. Providing meals at the Center and at the participants’ homes, if necessary.
 2. Providing nourishing, palatable, well-balanced meals that meet the recommended daily nutritional (RDA) and dietary needs of each participant.
 3. Providing special diets to include enteral and parenteral nutrition.
 4. Oversight, approval and menu planning by a Registered Dietitian.

**Chapter 3 ~ FINANCIAL Chapter 3 ~ FINANCIAL Chapter 3 ~ FINANCIAL Chapter 3 ~ FINANCIAL
FINANCIAL Chapter 3 ~ FINANCIAL**

I. FISCAL SOUNDNESS (§460.80(a))

- A. Describe any reserve requirements and other financial requirements set by the State in which the PACE Organization operates and demonstrate how the entity meets these requirements. Include any supporting documentation, as necessary.
- B. In the Documents part, provide independently certified 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. If the PACE program is a line of business of the applicant, it should provide audited statements relating to the legal entity. Audits are to include:
 - 1. Opinion of a certified public accountant.
 - 2. Statement of revenues and expenses.
 - 3. Balance sheet.
 - 4. Statement of cash flows.
 - 5. Explanatory notes.
 - 6. Management letters.
 - 7. Statements of changes in net worth.
 - 8. Actuarially certified statement of incurred but not reported claims. (If required by State licensure.)
- C. In the Documents part, provide a copy of the most recent year-to-date unaudited financial statement of the entity.
- D. In the Documents part, provide independently certified audited financial statements of guarantors, and lenders (organizations providing loans, letters of credit or other similar financing arrangements, excluding banks).
- E. If the entity is a public corporation or subsidiary of a public corporation, provide in the Documents part the most recent Annual Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, Form 10-K.

II. FINANCIAL PROJECTIONS II. FINANCIAL PROJECTIONS II. FINANCIAL PROJECTIONS II. FINANCIAL PROJECTIONS¹

In the Documents part, provide financial projections for a minimum of one year from the date of the latest submitted financial statement. Give projections from this date through one year beyond break-even. Describe financing arrangements and include all documents supporting these arrangements for any projected deficits. There must be evidence of financing arrangements for any projected deficit. (If the PACE organization has reached

¹ See the reference in the Introduction for the sources for purchasing the NAIC report forms and the instructions for completing the forms.

break-even, provide projections from this date until one year from anticipated date of execution of contract.)

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 the following:

Quarterly balance sheets for the applicant, using accrual accounting in conformity with GAAP. The National Association of Insurance Commissioners (NAIC) Financial Report #1 format may be used if also required for State licensure.

Quarterly statements of revenues and expenses for the legal entity. *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.* Give projections in gross dollars as well as on a per member per month basis. Quarters should be consistent with standard calendar year quarters. Include year end totals. If an organization has a category of revenue and/or expense that is not included in the present definitions, provide an explanation.

Quarterly Statements of Cash Flows

Statement and Justification of Assumptions - State major assumptions in sufficient detail to allow an independent financial analyst to reconstruct projected figures using only the stated assumptions. Include operating and capital budget breakdowns.

Stated assumptions should address all periods for which projections are made and include inflation assumptions. Details of minor assumptions will be verified on site. Justify assumptions to the extent that a knowledgeable reviewer would be convinced that they are reasonable. Base justification on such factors as the applicant's experience, the experience of other health plans. Describe hospital and health professional costs and utilization in detail.

III. INSOLVENCY (§460.80(b))

A. Describe the PACE Organization's provisions for the event of insolvency that include:

1. The continuation of benefits for the duration of the period for which capitation payment has been made;
2. Continuation of benefits to participants who are confined in a hospital on the date of insolvency until their discharge; and
3. Protection of participants from liability for payment of fees that are the legal obligation of the PACE Organization.

B. Provide documents in the Documents part that demonstrate the PACE Organization 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.*)

IV. FINANCIAL RISK IV. FINANCIAL RISKIV. FINANCIAL RISKIV. FINANCIAL RISKIV. FINANCIAL RISK

Insurance Protection: Use the Insurance Table to summarize insurance or other arrangements for major types of loss and liability. Complete the table *paceinsu.doc* in its file on the disk and place the hard copy in the Documents part.

V. FINANCIAL RECORD KEEPING AND REPORTING (§204-208)

- A. Describe how the PACE Organization's financial records and reports meet the regulatory requirements.
- B. How does the PACE Organization ensure that it will submit quarterly and annual certified financial statements in a format acceptable to CMS and the State.

**Chapter 4 ~ MARKETING Chapter 4 ~ MARKETING Chapter 4 ~
MARKETING Chapter 4 ~ MARKETING Chapter 4 ~ MARKETING**

I. MARKETING (§460.82)

- A. Provide copies of all marketing materials to be distributed by the PACE Organization as a permanent provider in the Documents part. [Note: ALL marketing materials must clearly state that PACE participants may be fully and personally liable for the costs of unauthorized or out-of-network services.]
- B. Please identify in which languages marketing materials will be available, at the indication of the State Administering Agency.
- C. Please provide an assurance that, once marketing materials have been approved by CMS and the State Administering Agency, they will be translated into all necessary languages. [Note: Once approved marketing materials have been translated, they must be submitted, along with an attestation of accurate translation, to the State Administering Agency, who will forward them to the CMS Regional Office. PACE Organizations may NOT utilize the English version of marketing materials until translated materials in the languages specified in Section B, and the accompanying attestation, have been received by the CMS Regional Office.]
- D. How does the PACE Organization ensure that its employees or its agents do not use prohibited marketing practices as described in §460.82(e)?

II. MARKETING PROJECTIONS

Provide in the Documents part a marketing plan with measurable enrollment objectives and a system for tracking effectiveness.

Chapter 5 ~ PACE SERVICES

I. REQUIRED SERVICES (§460.92/94)

Complete the table for PACE required health services. This file is *pacehsd.doc*. Place this table in the Documents part. For all draft contracts, please provide a timeline for contract execution.

II. SERVICE DELIVERY (§460.98)

Describe the following:

- C. Plan for providing care 24 hours a day, 7 days a week. Include your on-call process.
- D. Plan for integrating the participant's care and services across all settings (nursing facility, home, acute care, rehab.). Include what is communicated and how this information gets to the receiving facility.

III. PACE CENTERS (§460.98)

- A. Describe the location(s) of the PACE Center(s) in relation to its defined service area. How will there be sufficient capacity to allow routine attendance by participants?
- B. Describe the PACE Organization's plan to increase the number of PACE Centers, staff, or other PACE services when necessary, in order to provide for accessible and adequate services for participant.
- C. How does the PACE Organization ensure that the frequency of a participant's attendance at a center is determined by the interdisciplinary team, based on the needs and preferences of each participant?

IV. EMERGENCY CARE (§460.100)

- A. Provide the PACE Organization's written plan to handle emergency care, including hold harmless and prudent layperson standard provisions.
- B. Describe the process the PACE Organization will follow to:
 - 1. Explain to each participant how to recognize emergency care. Provide the explanation given to participants to enable them to recognize emergency care needs.
 - 2. Ensure that the participant or caregiver, or both, understand how to access emergency care, urgently needed care, out-of-network services, and non-emergency care after the PACE Center is closed.

V. INTERDISCIPLINARY TEAM (§460.102)

A. Describe the process for assigning each participant to a interdisciplinary team functioning at the PACE Center that the participant attends.

B. Identify all interdisciplinary team members:

Discipline	Name	Employee of PACE Organization?	Serve Primarily PACE Participants?
Primary Care Physician			
Registered Nurse			
Social Worker			
Physical Therapist			
Occupational Therapist			
Recreational Therapist or Activity Coordinator			
Dietitian			
PACE Center Manager			
Home Care Coordinator			
Personal Care Attendant			
Driver			
Other			

C. Please provide in the Documents part the position description for each of the interdisciplinary team members, ensuring compliance with the personnel requirements specified in 460.64.

D. Describe how the PACE Organization assures that each interdisciplinary team member will:

1. Regularly inform other team members of the medical, functional, and psychosocial condition of each participant.
2. Remain alert to pertinent input from other team members, participants, and caregivers. Incorporate assessments and communication into the participant's plan of care.
3. Document any changes in a participant's condition in the participant's medical record and reflect these changes on the care plan, if necessary.

- E. What are the procedures to assure confidentiality in the exchange of information between team members, contractors, and participants and their caregivers?

VI. PARTICIPANT ASSESSMENT (§460.104)

Explain the PACE Organization's procedures to assure that the interdisciplinary team will perform the following:

- A. Conduct an initial comprehensive assessment on each participant. Include the timeframe for completing the assessment during the enrollment process. Include the disciplines and criteria (for the assessment) specified in regulation.
- B. Promptly consolidate discipline-specific assessments into a single plan of care for each participant.
- C. Inform female participants that they are entitled to choose a qualified specialist for women's health services from the PACE Organization's provider network to furnish routine or preventive women's health services.

VII. REASSESSMENTS (§460.104)

- A. Explain the PACE Organization's process to reassess participants semi-annually, annually, whenever the participants health or psychosocial status changes or at the request of the participant or designated representative. Include the following procedures to:
- Reevaluate the participant's plan of care.
 - Discuss any changes in the plan of care with the interdisciplinary team.
 - Obtain approval of the revised plan from the interdisciplinary team and the participant or their designated representative.
 - Document all assessment and reassessment information in the participant's medical record.
 - Furnish any services included in the revised plan of care as a result of a reassessment to the participant as expeditiously as the participant's health condition requires.
 - Discuss procedures if a participant's or designated representative's request for care/service is denied.
 - Determine when additional disciplines will be included in the reassessment.
- B. Describe which interdisciplinary team members will be participating in periodic, annual, and semiannual reassessments.

VIII. PLAN OF CARE (§460.106)

- A. In the Documents part, include a sample of a plan of care.
- B. Explain how the team will use the plan of care to meet the participant's health and psychosocial needs.
- C. Explain the process the interdisciplinary team members will use to implement, coordinate, and monitor the effectiveness of the plan of care, whether services are furnished by PACE employees or contractors.
- D. Explain the process the interdisciplinary team members will use to reevaluate the plan of care on at least a semi-annual basis, including defined outcomes.
- E. Explain the process the interdisciplinary team members will use to document and update the plan of care in the participant's medical record.
- F. Describe how the participant or caregiver or both are brought into the care planning process.
- G. Describe how the plan of care will be consolidated among disciplines.

Chapter 6 ~ PARTICIPANT RIGHTS

I. BILL OF RIGHTS (§460.110-112)

In the Documents part, provide a copy of the Participant Bill of Rights. You may utilize the Participant Rights template found at www.cms.hhs.gov/pace/prtemp.pdf.

II. EXPLANATION OF RIGHTS (§460.112, 116-118)

- A. Summarize policies and procedures for informing participants of their rights and ensuring they understand those rights.
- B. Identify any principal languages other than English used in the service area. Explain how translator services will be obtained for these languages and how any additional translator/interpreter services will be obtained as needed.
- C. Summarize policies and procedures for staff education (including contract staff) of participant rights and ensuring staff understand those rights.
- D. Summarize policies and procedures for promoting participant rights. Describe the process for identifying, responding to, and rectifying violations of rights.

III. RESTRAINTS (§460.114)

Describe the PACE Organization's policies and procedures regarding the use of chemical or physical restraints, to include the following:

- Circumstances under which they may be used.
- Requirements for documentation.
- Symptoms that led to their consideration.
- Less restrictive approaches utilized.
- Evaluation of participant responses.
- Specific goals to be achieved by the use of restraints.
- Definition and examples of restraints allowed
- Staff training regarding the use of restraints, care of participants while restrained, hazards of restraints and alternative approaches, reduction or elimination in restraint use, and care plan requirements.

IV. GRIEVANCE AND APPEAL PROCESSES (§460.120 - 460.124)

- A. Provide a copy of the formal written grievance process in accordance with 460.120 (a-d) in the Documents part.
- B. Provide a copy of the information on grievances that will be provided annually to participants in the Documents part.

- C. Describe how grievance data will be collected, aggregated, analyzed and trended and included in the QAPI program.
- D. Provide a copy of the formal written appeals process, in accordance with Section 460.122, in the Documents part.
- E. Provide a copy of the information on appeals that will be provided annually to participants in the Documents part.
- F. Describe how appeal data will be collected, aggregated, analyzed and trended and included in the QAPI program.
- G. Describe the process for informing participants of their additional appeal rights under Medicare and/or Medicaid, including the process for filing further appeals.

Chapter 7 ~ QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT

I. QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT PLAN (§460.132)

A. Provide a copy of the PACE Organization's QAPI Plan in the Documents part.

6. Describe the specific ways the PACE Organization's QAPI plan meets the following requirements:

- Receives approval and revisions annually by the Board of Directors.
- Identifies areas in which to improve or maintain the delivery of services and patient care.
- Develops and implements plans of action to improve or maintain quality of care.
- Documents and disseminates to PACE staff and contractors the results from the QAPI program.

If this information is provided in the QAPI plan, please refer to the page in the plan.

II. MINIMUM REQUIREMENTS FOR QAPI (§460.134)

A. Describe the methodology the PACE Organization will use to demonstrate improved performance with regard to the following:

1. Utilization of PACE services, such as decreased inpatient hospitalizations and emergency room visits.
2. Caregiver and participant satisfaction.
3. Outcome measures that are derived from data collected during assessments, including data on the following: physiological well being, functional status, cognitive ability, social/behavioral functioning, and quality of life of participants.
4. Effectiveness and safety of staff-provided and contracted services, including the following: competency of clinical staff, promptness of service delivery, achievement of treatment goals and measurable outcomes.
5. Nonclinical areas, such as grievances and appeals, transportation services, meals, life safety, and environmental issues.

B. Specify the clinical practice guidelines and professional practice standards on which the PACE Organization's outcome measures and standards of care are based. Clinical practice guidelines are those national, regional, or area scientifically derived tools that are recognized as best practice patterns. Professional practice standards are defined by each State for each licensed group. Standards are also defined by professional organizations.

- C. Describe **how** the PACE Organization ensures that it meets or exceeds minimum levels of performance, established by CMS and the State, on standardized quality measures which are specified in the PACE program agreement.
- D. Describe **how** the PACE Organization ensures that all data used for outcome measures are collected timely and are accurate and complete. Please explain the standard codes and formats utilized.

III. INTERNAL QAPI ACTIVITIES (§460.136)

- A. Describe how the PACE Organization meets the following QAPI requirements:
 - 1. Uses a set of outcome measures to identify areas of exemplary or problematic performance.
 - 2. Takes actions targeted at maintaining or improving care.
 - 3. Incorporates actions resulting in performance improvement into standards of practice for the delivery of care; periodically tracks performance to ensure improvements are sustained over time.
 - 4. Sets priorities for performance improvement, and gives priority to improvement activities that affect clinical outcomes.
 - 5. Immediately corrects any identified problem that directly or potentially threatens the health and safety of a PACE participant.

This area should be addressed in the QAPI plan; please refer to the page number.

- B. Explain how the PACE Organization ensures that all interdisciplinary team members, employees, and contract providers are involved in the development and implementation of QAPI activities and are aware of the results of these activities.
- C. Identify the individual who is designated to coordinate and oversee implementation of QAPI activities. Explain how the quality improvement coordinator encourages a PACE participant and his or her representatives to be involved in QAPI activities, including providing information about their satisfaction or dissatisfaction with provider services.

IV. COMMITTEES WITH COMMUNITY INPUT (§460.138)

Describe any committee(s) established by the PACE Organization that use community input to perform the following:

- Evaluate data collected pertaining to quality outcome measures
- Address the implementation of, and results from, the quality assessment and performance improvement plan

- Provide input related to ethical decision-making, including end-of-life issues and implementation of the Patient Self-Determination Act.

V. ADDITIONAL QUALITY ASSESSMENT ACTIVITIESV. ADDITIONAL QUALITY ASSESSMENT ACTIVITIESV. ADDITIONAL QUALITY ASSESSMENT ACTIVITIESV. ADDITIONAL QUALITY ASSESSMENT ACTIVITIESV. ADDITIONAL QUALITY ASSESSMENT ACTIVITIES (§460.140)

Describe how the PACE Organization will meet external quality assessment and reporting requirements, as specified by CMS or the State administering agency, in accordance with §460.202. This should include the health care data system and data entry processes (both manual and electronic) that will be utilized to ensure data are collected in standardized formats.

Chapter 8 ~ PARTICIPANT ENROLLMENT AND DISENROLLMENT

I. ELIGIBILITY TO ENROLL (§460.150)

- A. How will the PACE Organization ensure that participants meet eligibility requirements for the PACE Program?
- B. Specify any additional site-specific eligibility conditions proposed.
 - 7. Specify the criteria used to determine whether or not a participant's health or safety would be jeopardized by living in a community setting.
- D. Specify how the level of care determination conducted by the State Administering Agency (or its delegate) is communicated to the PACE Organization.

II. ENROLLMENT PROCESS (§460.152)

- A. Describe the enrollment and intake processes, including:
 - Staff responsible for explaining the program to potential enrollees;
 - Obtaining appropriate medical and financial information releases;
 - The requirement that the PACE Organization be the sole service provider and guarantee access to all services, but not to a specific provider;
 - Timeframes for providing a list of employees and contractors who furnish care;
 - Applicable premium or Medicaid spend-down requirements.
 - Effective date of enrollment

Provide a copy of all enrollment policies and procedures.

Provide interview and/or enrollment scripts, assessment criteria, and other assessment forms utilized by appropriate staff during the enrollment process.

- B. Describe the process used to inform prospective enrollees that they have been denied enrollment and the procedures to inform CMS and the State of enrollment denials. Submit copies of form letters and procedures in the Documents part.
- C. Describe procedures the PACE Organization uses to direct prospective enrollees to other sources of care after it has been determined they are not eligible for PACE.

III. ENROLLMENT AGREEMENT (§460.154)

Submit a copy of the proposed enrollment agreement that includes all items referenced in the regulations in the Documents part.

IV. OTHER ENROLLMENT PROCEDURES (§460.156)

- A. Submit copies of the following in the Documents part:
 - The PACE membership card.
 - Emergency information to be posted in the participant's home.
 - Stickers to be applied to the Medicare/Medicaid cards.
 - Any other relevant materials that are distributed.
- B. Describe the process for ensuring that if there are changes in the enrollment agreement information at any time during the participant's enrollment, the PACE Organization will provide an updated copy of the information and explain the changes to the participant and his or her designated representative in a manner they understand.

V. VOLUNTARY DISENROLLMENT (§460.162)

- A. Provide a copy of the policy and procedure for voluntary disenrollment.
- B. Explain the process used to notify CMS and the State of the effective date of the voluntary disenrollment.

VI. INVOLUNTARY DISENROLLMENT (§460.164)

- A. Provide a copy of the policy and procedure for involuntary disenrollment.
- B. Identify the PACE staff members involved in involuntary disenrollment decisions and any safeguards which are in place to protect the rights of participants in these circumstances.
- C. Describe how the State is notified of a potential disenrollment and the process for providing reasonable advance notice to the participant.

VII. REINSTATEMENT IN OTHER MEDICARE/MEDICAID PROGRAMS (§460.168)

- A. Describe procedures the PACE Organization uses to direct voluntarily or involuntarily disenrolled participants to other sources of care.
- B. Describe procedures the PACE Organization uses to make appropriate referrals and ensure medical records are made available timely to new providers.
- C. Describe the process to reinstate the participant in other Medicare or Medicaid programs for which the participant is eligible.

VIII. REINSTATEMENT IN PACE (§460.170)

Describe the procedures to reinstate participants who have been disenrolled.

IX. DOCUMENTATION OF DISENROLLMENT (§460.172)

- A. Describe the documentation to verify a participant's voluntary and involuntary disenrollment. Include a copy of any forms used in the disenrollment process in the Documents part.
- B. Describe how disenrollments are analyzed in the Quality Assessment and Performance Improvement Program.

**Chapter 9 ~ PAYMENT Chapter 9 ~ PAYMENT Chapter 9 ~ PAYMENT Chapter 9 ~
PAYMENT Chapter 9 ~ PAYMENT**

I. PAYMENT TO PACE PROVIDERS (§460.180-182)

The Medicare and Medicaid monthly capitation payments will be the payment in full for services rendered to PACE participants, with the exception of premiums under certain circumstances.

II. MEDICARE AS SECONDARY PAYOR (§460.180)

- A. Describe the systems/procedures the PACE Organization will implement under the Medicare Secondary Payor provisions.
- B. Describe the systems/procedures the PACE Organization will use to avoid duplicate payment of health care services.

Chapter 10 ~ DATA COLLECTION, RECORD MAINTENANCE & REPORTING

I. MAINTENANCE OF RECORDS & REPORTING DATA (§460.200)

- A. Describe the PACE Organization's procedures to collect data, maintain records, and submit reports as required by CMS and the State. Include who has access to data and records.
- B. Submit the PACE Organization's policies on safeguarding data and records against loss, destruction, or unauthorized use for the longest of the following periods:
 - Period of time specified in State law.
 - Six years from the last entry date in the record.
 - For medical records of disenrolled participants, six years after the date of disenrollment.
 1. Include how all data are checked for accuracy.
 2. Include under what circumstances the original medical record would be released from the center.
 3. Include timeframes for completing medical record documentation (filing and authorized discipline documentation).
 4. Include processes to evaluate the completeness, logic and consistency of data on an ongoing basis.
- D. Confidentiality – Describe the PACE Organization's written policies and procedures on protecting the confidentiality of all data and records. Include what information may be copied and released to authorized individuals.
 1. Include how the Organization will comply with Federal (HIPAA) and State law regarding the release of participant medical information.
 2. Include the process for de-identifying Protected Health Information (PHI).
 3. Include the process for granting participants timely access to reviewing, copying, and requesting amendments to their medical records.

II. PARTICIPANT HEALTH OUTCOMES DATA (§460.202)

- A. Describe the PACE Organization's health information system that is designed to collect outcomes data.
- B. How does the PACE Organization assure that it will furnish data and information pertaining to its provision of participant care in the manner and at the time intervals specified by CMS and the State?

III. MEDICAL RECORDS (§460.210)

- A. How does the PACE Organization ensure that a comprehensive, complete, and accurate medical record is maintained in accordance with accepted

professional standards and is housed by the PACE Center providing services to the participant? Include:

- A list of what is contained in the medical record.
- What are the PACE Organization's acceptable forms of documentation.
- Storage procedures if the medical record becomes too large.
- How copies of medical record information will be promptly transferred between treatment facilities.
- How the primary author will authenticate the medical record entries.
- How the electronic data are held confidential.
- How all required documentation will be incorporated into one medical record at point of care or promptly thereafter (from other settings).
- How medical staff receive results of tests in a timely manner and how the system is evaluated for improvements.

B. Provide in the Documents part a copy of the participant consent form used before releasing any participant information.

readme file

PROGRAM FOR ALL-INCLUSIVE CARE FOR THE ELDERLY ~ PACE

Please read the introduction and instructions to the application for information on how to complete the application form and submit to regulatory agencies for review.

Files for this application:

Files are MS Word97. The applicant should fill in the application form, which is the entire Narrative Part of the application. Forms/tables should be placed in the Documents Part, along with other documents supplied by the applicant, i.e., provider contracts. Follow directions in the application format for placement of hard copy. Also, include the filled in tables as separate files on the application diskette that will be submitted.

paceapp.doc The basic application form

paceinsu.doc Insurance table

pacehsd.doc Table for arrangements for PACE required services

pacesetup.doc PACE Set-up Forms - banking information, systems

NOTE: The application also requires financial projections on specific report formats. See the application for the source of these formats.

PACEHSD ARRANGEMENTS FOR PACE REQUIRED SERVICES

Required Services	D=Direct C=Contract	Contract D=Draft E=Executed	Name of Provider or Employee
Multidisciplinary assessment/treatment planning			
Physician services			
Nursing services			
Social work			
Physical therapy			
Occupational therapy			
Speech therapy			
Services in the home			
Personal care and supportive services			
Nutritional counseling			
Recreational therapy			
Transportation			
Meals			
Medical specialty services including but not limited to:			
Anesthesiology			
Audiology			
Cardiology			
Dentistry			
Dermatology			
Gastroenterology			
Gynecology			
Internal medicine			
Nephrology			
Neurosurgery			
Oncology			
Ophthalmology			
Oral surgery			
Orthopedic surgery			

Required Services	D=Direct C=Contract	Contract D=Draft E=Executed	Name of Provider or Employee
Otorhinolaryngology			
Plastic surgery			
Pharmacy consulting services			
Podiatry			
Psychiatry			
Pulmonary disease			
Radiology			
Rheumatology			
Surgery			
Thoracic and vascular surgery			
Urology			
Laboratory tests, x-rays and other diagnostic procedures			
Drugs and biologicals			
Prosthetics and durable medical equipment, corrective vision devices such as eyeglasses and lenses, hearing aids, dentures, and repairs and maintenance for these items			
Acute inpatient care, including, but not limited to:			
Ambulance			
Emergency room care and treatment room services			
Semi-private room and board			
General medical and nursing services			
Medical surgical/intensive care/ coronary care unit, as necessary			
Laboratory tests, x-rays and other diagnostic procedures			

Required Services	D=Direct C=Contract	Contract D=Draft E=Executed	Name of Provider or Employee
Drugs and biologicals			
Blood and blood derivatives			
Surgical care, including the use of anesthesia			
Use of oxygen			
Physical, speech, occupational, and respiratory therapies			
Social services			
Nursing facility care, including, but not limited to:			
Semi-private room and board			
Physician and skilled nursing services			
Custodial care			
Personal care and assistance			
Drugs and biologicals			
Physical, speech, occupational and recreational therapies, if necessary			
Social services			
Medical supplies and appliances			
Additional services determined necessary by the multidisciplinary team			

INSURANCE COVERAGE

Type	Carrier	Entity Covered	Description: Deductibles, Co-insurance, Minimum & Maximum Benefits	Premiums	Period Policies are in Effect	Other Arrangements to Cover These Risks
Reinsurance						
Risk of insolvency						
Out-of-area emergency						
Malpractice 1. Plan						
2. Affiliated Providers						
General Liability						
Casualty						
Fire						
Theft						
Fidelity bond						

MEDICARE CONTRACTOR DATA

DATE:

ORGANIZATION NAME:

ORGANIZATION CONTACTS:

PRESIDENT or CEO:

CHIEF FINANCIAL OFFICER:

INFORMATION SYSTEMS CONTACT:

DATA EXCHANGE:

1. Method/Medium organization will use to send membership records (select one):

- ACXIOM, Inc
- MDCN (Medicare Data Communications Network)
- AT&T Global Network Services Dial-Up
- Connect-Direct (Network Data Mover –NDM)
- Other 3rd Party Vendor

2. Does organization want the Transaction Reply Information in (select one):

- Electronic Data Format
- Electronic Report Format

3. Does organization want the Monthly Membership Information in (select one):

- Electronic Data Format
- Electronic Report Format

Note: All other monthly reports are available only in Electronic Report Format.

CMS has a contract with ACXIOM for access to the Enrollment Database and the Group Health Plan Master file. You may purchase minimum services only. Your organization can contact them at:

ACXIOM, Inc.
9171 Oso Avenue
Chatsworth, CA 91311

Charles Johnson
1-818-715-5735
www.acxiom-med.com

If you elect to access the CMS Data Center, you must complete the forms in this section and send them to the address given in the instructions at the same time that you submit the application. Be sure to include the signature page.

