PACE Program Agreement

AGREEMENT No. **HXXXX**

An Agreement Between

The Secretary of the Department of Health and Human Services, who has delegated authority to the Administrator of the Centers for Medicare and Medicaid Services, hereinafter referred to as CMS, and _____, the State Administering Agency, hereinafter referred to as SAA,

and

_____ hereinafter referred to as the PACE Organization

The Secretary, in finding the PACE Organization to be an eligible organization by the Administrator of CMS and ___State Agency___, agrees to the following with the PACE Organization for the purposes of enacting sections 1894 and 1934 of the Social Security Act:

ARTICLE I

TERM OF AGREEMENT
[§460.32(a)(3)] ; **[§460.34]**

This Agreement is effective for the contract year beginning XXXXXXX through XXXXXXX and may be extended for subsequent contract years in the absence of a notice by a party (CMS, SAA, or the PACE Organization) to terminate the agreement. This agreement supersedes any previous understanding, agreement, arrangement or contract with respect to the provision of and/or the payment for PACE services. This Agreement is subject to termination as contained in Article IV.

The PACE Organization agrees to comply with all regulations or general instructions or other terms and conditions as CMS or the SAA may find necessary and appropriate from time to time for the administration of the PACE program.

ARTICLE II
GENERAL CONDITIONS

A. Governing Body **[§460.32(a)(4)]** ; **[§460.62]** ; **[§460.60]**

(1). The name and telephone number of the PACE Organization's program director and the names of all members of the governing body, and the name and phone number of a governing body member who will serve as a liaison between the governing body and CMS and the SAA is contained in

Appendix A.

(2). Any changes in names or telephone numbers shall be reported to CMS and to the SAA prior to the effective date of the change(s).

B. PACE Structure **[§460.32(a)(4)] ; [§460.60]**

(1). A description of the organizational structure of the PACE Organization, including the relationship to, at a minimum, the governing body, program director, medical director, and to any parent, affiliate or subsidiary entity is shown in **Appendix B.**

(2). A PACE Organization planning a change in organizational structure shall notify CMS and the SAA, in writing, at least 14 days before the change takes effect.

C. Service Area and PACE Site(s) **[§460.32(a)(1)]**

(1). The PACE Organization shall furnish PACE services only to participants who live within the designated service area, approved by the SAA and CMS (except as provided in §460.70(b)(2)), which is identified by zip code, county, perimeter street boundaries, census tract, block, or tribal jurisdictional area (as applicable).

(2). The PACE Organization shall identify the sites at which it will perform PACE services. Any changes in the designated service area and/or the site(s) identified in this agreement must be approved by CMS and the SAA prior to effecting such changes. The designated service area and site(s) are included in **Appendix C.**

D. Participant Bill of Rights **[§460.32(a)(5)]; [§460.110 and §460.112]**

The PACE Organization shall make available to all enrollees a list and explanation of the rights to which they are entitled. The PACE Organization shall assure that those rights and protections are provided. The participant Bill of Rights that will be used to satisfy this requirement is included in **Appendix D.**

E. Services **[§460.32(a)(8)] ; §460.92 and §460.94]**

The PACE Organization agrees to make available comprehensive health care services that include, at a minimum, all services required by 42 CFR **§**460.92 and 42 CFR **§**460.94.

F. Eligibility, Enrollment and Disenrollment **[§460.32(a)(7) & §460.32(b)(1)]; [§460.150] [§460.160(b)(3)(ii)]; [§460.162]; [§460.164]**

(1). The PACE Organization shall consider for enrollment and enroll only those persons who: are 55 years or older, are determined by the SAA to need the level of care required under the State Medicaid plan for coverage of nursing facility services, are able to live in a community setting without jeopardizing their health or safety, and reside in the organization's approved designated service area.

(2). The PACE Organization's eligibility and enrollment policies, including the

criteria used to determine if persons are able to live in a community setting without jeopardizing their health or safety, is contained in **Appendix E.**

(3). The SAA, in consultation with the PACE Organization, makes a determination of continued eligibility based on a review of the participant's medical record and plan of care. The criteria used to make the determination of continued eligibility are contained in **Appendix E.**

(4). The PACE Organization may establish other enrollment criteria in addition to that found in Article II F(1) of this Agreement that support decisions to not enroll persons because of certain circumstances. This criteria, however, shall not modify the criteria in Article II F(1) above. All additional enrollment criteria, if any, are specified in **Appendix F.**

(5). The PACE Organization agrees that any participant, for any reason, may voluntarily disenroll and**,** upon doing so, is not liable for any additional or penalty payments. The voluntary disenrollment policy is contained in **Appendix G.**

(6). The PACE Organization may not involuntarily disenroll a participant except for specific causes. The PACE Organization's involuntary disenrollment policy is located in **Appendix H.**

G. Grievance and Appeals **[§460.32(a)(6)]; [§460.122]; [§460.124]**

(1). All participants are afforded the right to grieve a PACE Organization's medical and non-medical decisions. They also have the right to appeal the PACE Organization's refusal to provide a particular care-related service or its decision not to pay for a service received by a PACE participant. Internal grievance and appeal procedures for participants are contained in **Appendix I.**

(2). PACE participants will be informed, in writing, of his or her appeal rights under Medicare or Medicaid managed care, or both. PACE participants will be assisted in choosing which to pursue if both are applicable. The additional appeal rights procedures under Medicare or Medicaid are contained in **Appendix J.**

H. Quality Assessment and Performance Improvement **[§460.32(a)(9), (a)(10), (a)(11)]; [§460.130, §460.134(c), §460.136, §460. 140]; [§460.202(b)]**

(1). A description of the PACE Organization's quality assessment and performance improvement program is contained in **Appendix K.**

(2). The PACE organization shall meet or exceed minimum levels of performance on standardized quality measures as established by CMS and the SAA. The minimum level of performance is: The organization will achieve an immunization rate for both influenza and pneumococcal vaccinations of 80% for the participant population that is appropriate. (Rate will exclude those participants who have had prior immunization or the vaccine is medically contraindicated).

(3). The PACE Organization shall furnish data and information on participant care activities, as established by CMS and the SAA. These data are contained in **Appendix L.**

I. Data Collection and Reporting Requirements **[§460.200(a)(b)(c) and §460.204];**

[§460.70]

(1). The PACE Organization shall collect data, maintain records and submit reports as required by CMS and the SAA. The PACE Organization shall allow CMS and the SAA access to data and records including, but not limited to, participant health outcomes data, financial books and records, medical records, personnel records, any aspect of services furnished, reconciliation of participants, benefit liabilities and determination of Medicare and Medicaid amounts payable**.**

(2). The PACE Organization agrees to require that all related entities, contractors or subcontractors agree that the SAA, the U.S. Department of Health and Human Services, CMS, or their designee(s) have the right to inspect, evaluate and audit any pertinent contracts, books, documents, papers, and records of any related entity contractor(s) or subcontractor(s) involving transactions related to this Agreement.

ARTICLE III
PAYMENT
[§460.32(a)(12)]

For each enrolled participant who is Medicare and/or Medicaid eligible, the PACE Organization will be paid a prospective, monthly capitation amount.

A. For Participants Eligible for Medicare **[§460.180]**

(1). Separate rates are established for Part A and Part B. For a participant entitled to Part A benefits and enrolled under Part B, both the Part A and Part B rates are paid. For a participant who is entitled to Part A benefits but not enrolled under Part B, only the Part A rate is paid. For a participant enrolled under Part B but not entitled to Part A benefits, only the Part B rate is paid.

(2). The Medicare payment amount is described in **Appendix M.**

B. For Participants Eligible for Medicaid **[§460.182]**

(1). The monthly capitated Medicaid payment amount is negotiated between the PACE Organization and the SAA. This payment amount is specified in **Appendix M.**

(2). The SAA shall describe the enrollment/disenrollment reconciliation procedures, to adjust for the difference between the estimated number of participants on which the prospective monthly payment was based and the actual number of participants claimed in that month. The reconciliation method is contained in **Appendix N.**

ARTICLE IV
TERMINATION OF THE AGREEMENT
[§460.32(a)(13)] [§460.50, §460.52, §460.54]

A. CMS or the SAA may terminate this Agreement at any time for cause, including, but not limited to: uncorrected deficiencies in the quality of care furnished to participants, the PACE Organization's failure to comply substantially with the conditions for a PACE program, or non-compliance with the terms of this Agreement.

B. The PACE organization may terminate this agreement after timely notice to CMS, the SAA and the participants. Notifications shall be made as follows: 90 days before termination to CMS and the SAA and 60 days before termination to the participants.

C. The PACE Organization's detailed written plan for phase-down, in the event of termination, is included in **Appendix O.**

ARTICLE V
REQUIREMENTS OF LAWS AND REGULATION
[§460.32(a)(2)]

A. The PACE Organization agrees to comply with all applicable Federal, State, and local laws and regulations, including, but not limited to:

(1). Sections 1894 and 1934 of the Social Security Act as implemented by regulations at 42 CFR Part 460;
(2). Title VI of the Civil Rights Act of 1964 as implemented by regulations at 45 CFR Part 84;
(3). The Age Discrimination Act of 1975 as implemented by regulations at 45 CFR Part 91;
(4). The Americans with Disabilities Act; and
(5). Other laws applicable to the receipt of Federal funds.

ARTICLE VI
CHANGES TO THE PROGRAM AGREEMENT

The Parties agree that CMS has the authority to incorporate any additional terms agreed upon by all parties or revise any terms of this agreement and its accompanying appendices that:

(1). Are subject to periodic readjustment;
(2). Are outmoded as a result of an organizational change made by the PACE Organization;
(3). Are outmoded as a result of a contractual modification, initiated by a Party; or
(4). Is required by a change in applicable Federal, State, or local laws and regulations.

CMS shall provide the PACE Organization and the SAA with a written notification of any revisions made to the program agreement and/or its appendices, along with the revised program agreement pages. Upon notification, the parties shall notify CMS, in writing, of any disagreement with the terms of the revision(s). Absent written notification to CMS that a party disagrees with the terms contained in CMS's notification, revisions shall become effective thirty (30) days after the date of the initial notification to the parties.

ARTICLE VII
STATE ADMINISTERING AGENCY REQUIREMENTS

Compliance and State Monitoring of the PACE Program

The SAA further assures that its responsibilities under section 1934 of the Social Security Act will be met. All relevant provisions are included in the contract with the PACE entities, either as contractor or SAA responsibility. Both scheduled and unscheduled on-site reviews will be conducted by SAA staff.

A. Readiness Review: The SAA will perform a Readiness Review of the applicant entity that assures the entity has fully developed its policies and procedures, obtained commitments from key staff, developed its solvency plan and has a facility that meets State and Federal requirements at the time of the application, in accordance with Section 460.12(b)(1).

B. Monitoring During Trial Period: During the trial period, the SAA, in cooperation with CMS, will conduct comprehensive reviews of a PACE organization to ensure compliance with State and Federal requirements.

At the conclusion of the trial period, the SAA, in cooperation with CMS, will continue to conduct reviews of a PACE organization, as appropriate, taking into account the quality of care furnished and the organization's compliance with State and Federal requirements.

C. Annual Monitoring: The SAA assures that at least annually it will reevaluate whether a participant meets the level of care required under the State Medicaid plan for coverage of nursing facility services. The SAA understands that this determination may be waived if there is no reasonable expectation of improvement or significant change in the participant's conditions because of the severity of a chronic condition or the degree of impairment of functional capacity. The SAA assures that it will make reviews conducted in accordance with Sections 460.190 and 460.192 available to the public upon request.

D. Monitoring of Corrective Action Plans: The SAA assures it will monitor the effectiveness of corrective actions required to be taken by the PACE organization.

Enrollment and Disenrollment

A. A description of the SAA's enrollment process, to include the criteria for deemed continued eligibility for PACE, in accordance with Section 460.160 (b)(3), is contained in **Appendix P**.

B. 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 is contained in **Appendix Q**.

C. 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, is contained in **Appendix R**.

D. A description of the SAA's disenrollment process is contained in **Appendix S**.

E. The SAA assures that before an involuntary disenrollment is effective, it will review and determine in a timely manner that the PACE organization has adequately documented grounds for disenrollment.

F. In the event a PACE participant disenrolls or is disenrolled from a PACE program, the SAA will work with the PACE organization to assure the participant has access to care during the transitional period.

G. The SAA assures it will facilitate reinstatement in other Medicaid/Medicare programs after a participant disenrolls.

H. The SAA assures that the State PACE requirements and State procedures will specify the process for how the PACE organization must submit participant information to the SAA.

Marketing

The SAA assures that a process is in place to review PACE marketing materials in compliance with Section 460.82(b)(ii).

Decisions that require joint CMS/SAA Authority

A. Waivers: The SAA will determine whether regulatory waiver requests submitted by PACE organizations will be considered by CMS and will consult with CMS on those requests. Approved waiver requests are described in **Appendix T**.

B. Service Area Designations: The SAA will consult with CMS on changes proposed by the PACE organization related to service area designation.

C. Organizational Structure: The SAA will consult with CMS on changes proposed by the PACE organization related to organizational structure.

D. Sanctions and Terminations: The SAA will consult with CMS on termination and sanctions of the PACE organization.

State Licensure Requirements

The SAA assures that Life Safety Code requirements are met for facilities in which the PACE organization furnishes services to PACE participants in accordance with Section 460.72(b), unless CMS determines that a fire and safety code imposed by State law adequately protects participants and staff.

AGREEMENT No. HXXXX

In witness whereof, the parties hereby execute this agreement.

For the PACE Organization

Printed Name Title

Signature Date

Address

For the State

Printed Name Title

Signature Date

Address

For the Centers for Medicare and Medicaid Services

Printed Name Title

Signature Date

Address

PROGRAM AGREEMENT APPENDICES
APPENDIX A: NAMES AND CONTACT LIST

1. Name of Program Director:
Telephone Number:

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

Telephone Number:

3. Governing body/Board of Directors:

APPENDIX B: ORGANIZATIONAL STRUCTURE

APPENDIX C: SERVICE AREA AND PACE SITE(S)

1. Identify the entire catchment area the PACE program will be covering.

2. Identify the catchment area by zip codes (if the entire county is not included in the service area), and counties or tribal jurisdictional areas (if applicable).

3. LIST THE NAME AND ADDRESS OF EACH PACE SITE(S).

APPENDIX D: PARTICIPANT BILL OF RIGHTS

APPENDIX E: ELIGIBILITY AND ENROLLMENT POLICIES; AND CONTINUED ELIGIBILITY CRITERIA

APPENDIX F: ADDITIONAL ENROLLMENT CRITERIA

APPENDIX G: VOLUNTARY DISENROLLMENT POLICY

APPENDIX H: INVOLUNTARY DISENROLLMENT POLICY APPENDIX I: INTERNAL GRIEVANCE AND APPEAL PROCEDURES

APPENDIX I: INTERNAL GRIEVANCE AND APPEAL PROCEDURES

APPENDIX J: ADDITIONAL APPEAL RIGHTS UNDER MEDICARE OR MEDICAID

APPENDIX K: QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT PROGRAM

APPENDIX L. PARTICIPANT DATA

These data will be reported electronically into the CMS database, known as "HPMS":

1) Routine Immunizations:

Definition: PACE participants who received routine immunizations during the reporting year.

What data will be reported:

1) Number of participants who received the flu immunization this year;
2) Number of participants who have received the pneumococcal immunization in the last ten years;
3) Total number of participants at the PACE organization.
4a) Number of participants not immunized for flu
4b) Number of participants not immunized for pneumococcal
5) Reason for not immunizing

Frequency: During the inoculation time period (e.g. Sept. to Jan.)

How to use the measure: Compare the number of PACE participants who were enrolled during the reporting year to the number of participants who received routine immunizations (flu and pneumococcal) during the reporting year.
Minimum levels of Performance: The organization will achieve an immunization rate for both influenza and pneumococcal vaccinations of 80 % for the participant population that is appropriate. (Rate will exclude those participants who have had prior immunization or the vaccine is medically contraindicated).

2) Grievances and Appeals

Definition: Grievances are defined as either a written or oral complaints that expresses dissatisfaction with service delivery or the quality of care provided. Appeals are defined as a written complaint for the noncoverage or nonpayment of a service or item.

What data will be reported:

1. Total number of participants during the quarter;
2. Total number of grievances filed during the quarter;
3. Total number of appeals filed during the quarter;
4. Source of each grievance or appeal (participant, family, caregiver, etc.);
5. Date of initiation of each grievance or appeal; and
6. Date of resolution of each grievance or appeal.

Frequency: Quarterly

How to use the measure: Monitor trends and patterns. The actual

number of grievances and appeals alone should not be viewed as an indicator of a problem. The high number of grievances could mean that participants are encouraged to speak up for themselves and voice their concerns.

3) Enrollments

Definition: Individuals enrolled in the PACE program by month.

What data will be reported: Number of individuals who enrolled in the program.

Frequency: Quarterly

How to use the measure: Monitor trends and patterns to determine if there are any accessibility issues and to determine if the PACE organization has sufficient financial resources to conduct appropriate marketing activities. This information can also be used to evaluate the PACE organization's ability to maintain an appropriate census.

4) Disenrollments

Definition: Participants who disenrolled from the program for reasons other then death.

What data will be reported:

1. Total number of participants;
2. Number of voluntary disenrollments;
3. Number of involuntary disenrollments; and
4. Reason for each disenrollment: leaving the service area, failure to pay premium, disruptive or threatening behavior, no longer meets States level of care, program agreement with CMS terminates or not renewed, organization is unable to offer services due to loss of State license, keep personal physician, wishes to access out of network or other.

Frequency: Quarterly

How to use the measure: Utilize this information to determine if there are any problems with site operations, such as accessibility, provision of services, etc. that are causing voluntary disenrollments. In addition, this information can be used to review the organization's policies on involuntary disenrollments.

5) Prospective Enrollees

Definition: Potential participants who were interviewed, met eligibility requirements but did not enroll in the PACE program.

What data will be reported:

1) Number of potential participants who were interviewed but did not enroll in the PACE program by aggregate reason; and
2) Indicate the category that explains the reason each potential participant did not enroll, e.g. not safe to remain in the community, mental health concerns, lack of support network, requiring 24-hour care, preference for own physician, preference for other health care provider or institution, financial reason to avoid share of cost, unwilling to comply with treatment plan, or other with explanation.

Frequency: Quarterly

How to use the measure: This information can be utilized to determine if the PACE organization is following the appropriate eligibility criteria and to determine if the organization is conducting appropriate marketing activities.

6) Readmissions

Definition: PACE participants re-admitted to an acute care hospital (excluding hospitalizations for diagnostic tests) in the last 30 days.

What data will be reported:

1. Total number of participants;
2. Total number of participants admitted to the hospital in the last 30 days;
3. Specific reason, including diagnosis, for participant's admission;

Frequency: Quarterly

How to use the measure: Review those with high usage to determine if intervention by the PACE organization could have prevented some of the hospitalizations. Readmission for the same reason in a 30-day period could indicate that the length of stay is too short or there is inadequate follow-up care by the PACE organization. Conduct quarterly comparisons to get a total picture of the care provided by the organization.

7) Emergent (unscheduled) Care

Definition: PACE participants seen in the hospital emergency room (including care from a PACE physician in a hospital emergency department) or an outpatient department/clinic emergency, Surgicenter.

What data will be reported:

1. Total number of participants;
2. Total number of participants by (aggregate) same diagnosis and;
3. Specific reason including diagnosis.

Frequency: Quarterly

How to use the measure: Review those with high usage to determine if intervention by the PACE organization could have prevented some of the visits to the ER.

8) Unusual Incidents for Participants and the PACE site (to include staff if participant was involved)

Definition: Unanticipated circumstances, occurrences or situations which have the potential for serious consequences for the participants. **Examples include, but are not limited to**: falls at home or the adult day health center; falls while getting into the van; van accidents other than falls; participant suicide or attempted suicide; staff criminal records; infectious or communicable disease outbreaks; food poisoning; fire or other disasters; participant injury that required follow-up medical treatment; participant injury on equipment; lawsuits; medication errors and any type of restraint use. This is not an inclusive list, so we would expect PACE sites to submit quarterly information on any unanticipated situations that occur.

What data will be reported: Number of unusual incidents aggregated by reason

Frequency: Quarterly

How to use the measure: Analyze categories focusing on whether these incidents were preventable, what steps were taken to resolve the problem, and what changes are being made to improve prevention. Is there a pattern that indicates a need for follow-up to investigate health and safety issues and procedures? Is this a program problem (e.g. negligence by staff) or a participant problem (e.g. verbal outbursts by participant with mental illness or severe dementia)?

9) Deaths

Definition: Death of participants during the given reporting period.

What data will be reported:

1. Number of participants (can be aggregated by reason and setting, if same);
2. Number of deaths;
3. Setting of the participant's death; and
4. Cause of the participant's death.

Frequency: Quarterly

How to use the measure: Analysis to determine if there is a pattern indicating inappropriate setting for the participant or problems with accessibility to 24 hour care. Because of the link between the number of deaths and enrollment, this information may also indicate if the PACE organization is maintaining an appropriate census to remain fiscally viable.

The data submitted must come exclusively from the PACE organization, not the parent organization.
If the PACE organization has more than one site of care/treatment, each site must be identified separately.

APPENDIX M: MEDICARE AND MEDICAID PAYMENT AMOUNTS

Medicare:
Before January 1, 2004, Medicare payment to PACE organizations was based entirely on the Medicare Part A and Part B demographic aged rate for the county in which the participant lived, adjusted by a frailty factor of 2.39. This payment was referred to as the demographic rate. As of January 1, 2004, PACE organizations began the transition to risk adjusted payment. This payment methodology reflects the organization level frailty of each PACE organization's enrollees. Under this new methodology, individual enrollee payment rates comprise the sum of the individual risk score and the organization frailty score multiplied by the risk adjustment county rate.

The risk/frailty score for community-dwelling participants is based on the CMS – Hierarchical Conditions Category (CMS-HCC) community model used in the Medicare Advantage program, which is based on diagnostic information submitted by PACE organizations, plus an organization-specific frailty score. To minimize the impact of risk adjusted payment, it is being phased in over time. During phase in, payment comprises a blend of the demographic rate (multiplied by 2.39) and the risk adjusted rate. In 2008, risk adjustment will be fully phased in. Details regarding risk adjusted payment can be found in the 2004 Advance Notice of Methodological Changes for Medicare Advantage and Part D Payment (Advance Notice). Changes to risk adjusted payment can be found in later Advance Notices.

A separate risk adjustment model for PACE participants who were paid under the ESRD payment system or who had functioning kidney transplants was fully implemented in 2005. This risk adjustment model has three payment modes: dialysis patient, transplant patient and functioning graft patient. The details of ESRD payment can be found in the 2005 Advance Notice. Changes to ESRD payment can be found in later Advance Notices.A notice of proposed changes to the Medicare payment methodology is published in February of each year in the Advance Notice and is followed by a two week comment period. Final changes are announced in the Announcement of MA Payment Rates (Announcement) on the first Monday in April of each year and are effective for the following year.

Medicare Part D Payment:
PACE organizations are required to annually submit two Part D bids: one for a Plan Benefit Package (PBP) for dually eligible enrollees and one for a PBP for Medicare-only enrollees.

The Part D payment to PACE organizations comprises several pieces, including the direct subsidy, reinsurance payments, and risk sharing. Payments for eligible enrollees of either PBP will include a low-income premium subsidy for basic Part D benefits. Payments for dual eligible enrollees will also include a low income cost sharing subsidy, an additional amount to cover nominal cost sharing

amounts (“2% capitation”), and an additional premium payment in situations where the PACE plan’s basic Part D beneficiary premium is greater than the regional low-income premium subsidy amount.

Direct Subsidy – The direct subsidy is a capitated per member per month payment that is equal to the product of the plan’s approved Part D standardized bid and the beneficiary’s health status adjustment factor, minus the plan’s monthly beneficiary premium. CMS payment of the Part D Direct Subsidy is for the basic Part D benefit only and excludes Part D supplemental benefits. PACE dual-eligible plans should not include any supplemental benefits; PACE Medicare-only plans will always have supplemental benefits.

Reinsurance Subsidy – The reinsurance subsidy is a federal subsidy for 80 percent of allowable drug costs above the out-of-pocket threshold, net of any other remuneration (e.g., rebates, coupons, etc.). It is subject to cost-based reconciliation. Because enrollees in Medicare-only PACE plans will not have any out-of-pocket expenditures, they will never reach the catastrophic phase of the benefit, and reinsurance payments will never be made to PACE Medicare-only plans. Low-income cost sharing subsidies paid on behalf of enrollees in PACE dual-eligible plans will count toward such enrollees’ out-of-pocket expenditures and, hence, it is possible that dual eligible PACE enrollees will reach the catastrophic phase of the benefit. Note that, because CMS makes a supplemental payment to cover the nominal cost sharing that a dual eligible Part D beneficiary would have to pay were they not enrolled in a PACE plan, and because this supplemental cost sharing is not attributable to beneficiary out-of-pocket spending, the starting point of the catastrophic phase of the benefit is extended slightly.

Risk Sharing – Risk sharing is designed to limit a plan’s exposure to unexpected expenses not already included in the reinsurance subsidy or taken into account through health status risk adjustment. The federal government and the plan share the profits or losses resulting from expenses for the standard benefit within defined symmetrical risk corridors around a target amount. The target amount for the Medicare-only plan is the same as for non-PACE plans: the sum of all direct subsidy and premium payments over the year. For dual eligible plans, the target amount will be calculated as the sum of all direct subsidy, premium, and 2% capitation payments.

Low Income Subsidies – Low income subsidies are government payments on behalf of eligible beneficiaries that cover part or all of the premium amount and part of any cost sharing that they face. Dual eligible beneficiaries will be deemed eligible for the full low income subsidy amounts. LIS premium payments will cover the entire beneficiary premium for enrollees in dual-eligible PACE plans, and may cover part or all of the Basic Part D premium for enrollees in Medicare-only PACE plans, depending on the enrollees’ low income subsidy eligibility level. Note that Medicare-only enrollees are responsible for paying the entire Part D

supplemental premium. LIS cost sharing subsidies are only paid on behalf of enrollees in dual-eligible PACE plans, since the benefit structure of Medicare-only PACE plans does not include cost sharing.

Medicaid:

APPENDIX N: STATE ENROLLMENT/DISENROLLMENT RECONCILIATION METHODOLOGY

APPENDIX O: TERMINATION PHASE - DOWN PLAN

APPENDIX P: SAA ENROLLMENT PROCESS

APPENDIX Q: SAA OVERSIGHT OF PO ADMINISTRATION OF SAFETY CRITERIA

APPENDIX R: INFORMATION TO BE PROVIDED BY THE SAA TO ENROLLEES

APPENDIX S: SAA DISENROLLMENT PROCESS

APPENDIX T: REGULATORY WAIVERS

APPENDIX U- MEDICARE PART D

The Centers for Medicare & Medicaid Services (hereinafter referred to as “CMS”) and _____ , a Medicare managed care organization (hereinafter referred to as the PACE Organization) agree that the PACE Organization shall operate a Voluntary Medicare Prescription Drug Plan pursuant to sections 1860D-1 through 1860D-42 (with the exception of sections 1860D-22 and 1860D-31) of the Act.

This agreement is made pursuant to 42 CFR Part 423, Subpart K (to the extent that waivers of those provisions have not been granted pursuant to 42 CFR §423.458(d)) and 42 CFR Part 460, Subpart C, of the PACE regulations.

Article I
Medicare Prescription Drug Benefit

A. The PACE Organization agrees to operate a Medicare Prescription Drug Benefit as described in its application and related materials, including but not limited to all the attestations contained therein and all supplemental guidance provided by CMS. In addition, the PACE Organization agrees to comply with the provisions of this Appendix, which incorporates in its entirety the Medicare Part D Application for New PACE Organizations. The PACE Organization also agrees to operate in accordance with sections 1860D-1 through 1860D-42 of the Act (with the exception of sections 1860D-22 and 1860D-31), the regulations at 42 CFR §423.1 through 42 CFR §423.910, with the exception of Subparts Q, R and S and other sections of 42 CFR Part 423 specifically waived for PACE Organizations (the PACE waivers are attached to this Appendix as Attachment A), the abbreviated application, the PACE regulations at 42 CFR Part 460, as applicable, as well as all other applicable Federal statutes, regulations, and policies. This Appendix is deemed to incorporate any changes that are required by statute to be implemented during the term of this Appendix and any regulations or policies implementing or interpreting such statutory provisions.

B. CMS agrees to perform its obligations to the PACE Organization consistent with the regulations at 42 CFR §423.1 through 42 CFR §423.910, as applicable, sections 1860D-1 through 1860D-42 of the Social Security Act, as applicable, and the abbreviated application, as well as all other applicable Federal statutes, regulations, and policies.

C. CMS agrees that it will not implement, other than at the beginning of a calendar year, regulations under 42 CFR Part 423 that impose new, significant regulatory requirements on the PACE Organization. This provision does not apply to new requirements mandated by statute.

D. This Appendix is in no way intended to supersede or modify 42 CFR, Part 423 or Part 460. Failure to reference a regulatory requirement in this Appendix does not affect the applicability of such requirements to the PACE Organization and CMS.

Article II
Functions to be Performed by the PACE Organization

A. ENROLLMENT

Part D eligible participants enrolled in a PACE plan that offers a Medicare Prescription Drug Plan must receive qualified prescription drug coverage through the PACE Organization's Part D plan pursuant to 42 CFR 423.30(c).

B. PRESCRIPTION DRUG BENEFIT

1. The PACE Organization agrees to provide the basic prescription drug coverage as defined under 42 CFR 423.100 to all Part D eligible PACE beneficiaries and, to the extent applicable, supplemental benefits as defined in 42 CFR 423.100 and in accordance with Subpart C of 42 CFR Part 423 to all Part D eligible beneficiaries. The PACE Organization also agrees to provide Part D benefits as described in the PACE Organization's Part D bid(s) approved each year by CMS.

2. The PACE Organization agrees to calculate and collect beneficiary Part D premiums, to the extent applicable, in accordance with 42 CFR §§ 423.286 and 423.293.

C. DISSEMINATION OF PLAN INFORMATION

1. The PACE Organization agrees to disclose information related to Part D benefits to beneficiaries in the manner specified in the PACE regulations at 42 CFR §460.82.

2. Any PACE Organization that utilizes a Part D formulary agrees to provide notice regarding formulary changes and to educate participants and providers concerning its formulary in accordance with 42 CFR §423.120(b).

3. Approval of marketing materials shall be governed by 42 CFR §460.82 of the PACE regulations.

D. QUALITY ASSURANCE/UTILIZATION MANAGEMENT

1. The PACE Organization will operate quality assurance, cost and utilization management, and medication therapy management as required in 42 CFR §§ 460.102, 460.104, 460.106, and Subpart H of the PACE regulations to the extent these requirements have relevance to Part D and do not exceed the corresponding requirements under 42 CFR §§ 423.153 and 423.162.

2. The PACE Organization will support electronic prescribing in accordance with 42 CFR §423.159.

E. APPEALS AND GRIEVANCES

The PACE Organization agrees that any appeals and grievances regarding Part D issues will be subject to the requirements of 42 CFR §§ 460.120, 460.122 and 460.124 of the PACE regulations governing grievances and appeals.

F. PAYMENT TO PACE ORGANIZATION

The PACE Organization and CMS agree that payment paid for Part D services

under this Appendix will be governed by § 1894(d) of the Act and the rules in Subpart G of 42 CFR Part 423.

G. BID SUBMISSION AND REVIEW

1. If the PACE Organization intends to participate in the Part D Program for the next program year, the PACE Organization agrees to submit the next year's Part D bid, including all required information on premiums and benefits, by the applicable due date as provided in Subpart F of 42 CFR Part 423, unless a waiver is granted pursuant to 42 CFR §423.265(b), so that CMS and the PACE Organization may conduct negotiations regarding the terms and conditions of the proposed bid and benefit plan renewal.

H. COORDINATION WITH OTHER PRESCRIPTION DRUG COVERAGE

1. The PACE Organization agrees to comply with the coordination requirements of State Pharmacy Assistance Programs (SPAPs) and, as applicable, agrees to comply with coordination requirements of other plans that provide prescription drug coverage as described in 42 CFR §§423.464(a)-(b),(d)-(e), (f)(1) and (3).

2. The PACE Organization agrees that Medicare Secondary Payer procedures will be governed by 42 CFR §460.180(d) of the PACE regulations.

I. SERVICE AREA AND PHARMACY ACCESS

1. The PACE Organization agrees to provide Part D benefits to Part D eligible PACE enrollees in the service area for which it has been approved by CMS to offer PACE benefits.

2. The PACE Organization agrees to ensure adequate access to Part D covered drugs at out-of-network pharmacies in accordance with 42 CFR §§460.90(b), 460.92(q) and 460.100.

3. The PACE Organization agrees to adjudicate prescription drug claims in a timely and efficient manner in compliance with CMS standards.

J. COMPLIANCE PLAN/PROGRAM INTEGRITY

The PACE Organization agrees that it will develop and implement a compliance plan that applies to its Part D-related operations, consistent with 42 CFR §§423.504(b)(4)(vi)(F)-(H) and 42 CFR §§460.32, 460.60-68, 460.71 and 460.80.

K. LOW-INCOME SUBSIDY

The PACE Organization agrees that it will participate in the administration of subsidies for low-income individuals according to Subpart P of 42 CFR Part 423.

L. BENEFICIARY FINANCIAL PROTECTIONS

The PACE Organization agrees to afford its enrollees protection from liability for payment of fees related to Part D prescription drug coverage that are the obligation of the PACE Organization in accordance with section 1894(b)(1)(A)(i) of the Act and 42 CFR §§ 460.70(e)(5) and 460.90(a).

M. RELATIONSHIP WITH RELATED ENTITIES, CONTRACTORS, AND SUBCONTRACTORS

1. The PACE Organization agrees that it maintains ultimate responsibility for adhering to, and otherwise fully complying with, all terms and conditions of this Appendix.

2. The PACE Organization shall ensure that any contracts or agreements with subcontractors or agents performing functions on the PACE Organization's behalf related to the operation of the Part D benefit are in compliance with 42 CFR §460.70 of the PACE regulation.

N. CERTIFICATION OF DATA THAT DETERMINE PAYMENT

The PACE Organization shall provide certifications in accordance with 42 CFR §423.505(k)(1-5).

Article III
Record Retention and Reporting Requirements

A. MAINTENANCE OF RECORDS

The PACE Organization agrees to maintain records and provide access in accordance with 42 CFR §423.505(d) and 42 CFR §§460.200(a)–(e), 460.202, 460.204, 460.208 and 460.210.

B. GENERAL REPORTING REQUIREMENTS

The PACE Organization agrees to submit information to CMS according to 42 CFR 460, Subpart L of the PACE regulations and the "Medicare Part D Reporting Requirements", a document issued by CMS and subject to modification each program year. The Reporting Requirements document specifies the abbreviated list of requirements applicable to PACE organizations.

C. CMS LICENSE FOR USE OF PLAN FORMULARY

If the PACE Organization develops a formulary, then the PACE Organization agrees

to submit to CMS its formulary information, including any changes to its formularies, and hereby grants to the Government [and any person or entity who might receive the formulary from the Government,] a non-exclusive license to use all or any portion of the formulary for any purpose related to the administration of the Part D program, as applicable.

Article IV
HIPAA Transactions/Privacy/Security

The PACE Organization agrees to comply with the confidentiality and enrollee record accuracy requirements specified in 42 CFR §§460.200(d)-(e) of the PACE regulations.

Article V
Appendix Term and Renewal

A. TERM OF APPENDIX

This Appendix is effective from the date of CMS' authorized representative's signature through December 31, 2007, and shall be renewable for successive one-year periods thereafter according to 42 CFR §460.34 of the PACE regulations. The PACE Organization shall begin delivering the Medicare prescription drug benefit services upon executing the signed PACE program agreement.

B. QUALIFICATION TO RENEW APPENDIX

1. In accordance with 42 CFR §423.507, the PACE Organization will be determined qualified to renew this Appendix annually only if—
   (a) CMS informs the PACE Organization that it is qualified to renew its Appendix; and
   (b) The PACE Organization has not provided CMS with a notice of intention not to renew in accordance with Article VII of this Appendix.

2. Although the PACE Organization may be determined qualified to renew its Appendix under this Article, if the PACE Organization and CMS cannot reach agreement on the Part D bid under Subpart F of 42 CFR Part 423, no renewal takes place, and the failure to reach agreement is not subject to the appeals provisions in 42 CFR Part 423, Subpart N or 42 CFR §460.54.

Article VI
Relationship Between Appendix and PACE Program Agreement

A. In the event that the PACE Organization's Program Agreement is terminated by any party, the provisions of this Appendix shall also terminate. In such an event, the PACE Organization shall provide notice to enrollees and the PACE Organization shall prepare a transitional plan of care as described in the Program Agreement as

well as in 42 CFR §460.52 of the PACE regulations.

B. The PACE Organization acknowledges that the termination or nonrenewal of this Appendix by either party may require CMS to terminate or non-renew the PACE Program Agreement in the event that such termination or non-renewal prevents the PACE Organization from meeting the requirements of 42 CFR §§ 460.80(a) and 460.92, in which case the PACE Organization must provide the notices as specified in Article VI.A. of this Appendix, as well as the notices specified under 42 CFR §460.52. The PACE Organization also acknowledges that the nonrenewal or termination of this Appendix by either party may prevent the PACE Organization from entering into a new Program Agreement with CMS for two years following such Appendix nonrenewal or termination where CMS determines that such non-renewal or termination will prevent the PACE Organization from meeting the requirements of 42 CFR §§460.80(a) and 460.92.

C. The termination of this Appendix by either party shall not, by itself, relieve the parties from their obligations under the Program Agreement to which this document is an Appendix.

Article VII
Nonrenewal of Appendix

A. NONRENEWAL BY THE PACE ORGANIZATION

1. The PACE Organization may non-renew this Appendix in accordance with 42 CFR §423.507(a).

2. If the PACE Organization non-renews this Appendix under this Article, CMS cannot enter into a Part D Appendix with the organization for 2 years unless there are special circumstances that warrant special consideration, as determined by CMS.

B. NONRENEWAL BY CMS

CMS may non-renew this Appendix under the rules contained in 42 CFR §423.507(b).

Article VIII
Modification or Termination of Appendix by Written Mutual Consent

This Appendix may be modified or terminated by written mutual consent in accordance with 42 CFR §423.508.

Article IX
Termination of Appendix by CMS

CMS may terminate this Appendix in accordance with 42 CFR 423.509.

Article X
Termination of Appendix by the PACE Organization

A. The PACE Organization may terminate this Appendix in accordance with 42 CFR §423.510.

B. CMS will not enter into a Part D Appendix with any PACE Organization that has terminated its Appendix within the preceding two years unless there are circumstances that warrant special consideration, as determined by CMS

C. If the Appendix is terminated under section A of this Article, the Pace Organization must ensure the timely transfer of any data and files.

Article XI
Intermediate Sanctions

The PACE Organization shall be subject to sanctions and civil money penalties, consistent with Subpart O of 42 CFR Part 423.

Article XII
Severability

Severability of the Appendix shall be in accordance with 42 CFR §423.504(e).

Article XIII
Miscellaneous

A. DEFINITIONS: Terms not otherwise defined in this Appendix shall have the meaning given such terms at 42 CFR Part 423 or, as applicable, 42 CFR Part 460.

B. ALTERATION TO ORIGINAL APPENDIX TERMS: The PACE Organization agrees that it has not altered in any way the terms of the PACE Part D Appendix. The PACE Organization agrees that any alterations to the original text of the Appendix made by the PACE Organization shall not be binding on the parties.

C. ADDITIONAL CONTRACT TERMS: The PACE Organization agrees to include in this Appendix other terms and conditions in accordance with 42 CFR 423.505(j).

D. CMS APPROVAL TO BEGIN PROVIDING PART D: The PACE Organization agrees that it must complete CMS operational requirements including, but not limited to, establishing and successfully testing connectivity with CMS systems to process enrollment applications (or contracting with an entity qualified to perform such functions on the PACE Organization's behalf). To establish and successfully test

connectivity, the PACE Organization must 1) establish and test physical connectivity to the CMS data center, 2) acquire user identifications and passwords, 3) receive, store, and maintain data necessary to perform enrollments and send and receive transactions to and from CMS, and 4) check and receive transaction status information.

ATTACHMENT A

PART D WAIVERS

CMS is authorized to grant waivers of Part D program requirements where such a requirement conflicts with or duplicates a PACE requirement, or where granting such a waiver would improve the PACE Organization's coordination of PACE and Part D benefits. The following waivers are in effect for all PACE organizations.

Summary of Medicare Part D Regulatory Requirements Waived for PACE Organizations

Part D Regulation	Regulatory Requirement(s) Description
423.44	Involuntary disenrollment
423.48	Information about Part D
423.50	Approval of marketing materials and enrollment forms
423.104(g)(1)	Access to negotiated prices
423.112	Establishment of PDP service areas
423.120(a)	Access to covered Part D drugs
423.120(c)	Use of standardized technology
423.124	Out-of-network access to covered Part D drugs at out-of-network pharmacies
423.128	Dissemination of Part D plan information
423.132	Public disclosure of pharmaceutical prices for equivalent drugs
423.136	Privacy, confidentiality, and accuracy of enrollee records
423.153(a)-423.153(d)	Drug utilization management, quality assurance, and medication therapy management programs (MTMPs)
423.156	Consumer satisfaction surveys
423.162	Quality Improvement organization activities
423.265(b) ***Note: Automatic waiver applies to new or potential organizations that are not operational by the June deadline.*** ***Those organizations with effective program agreements must submit a Part D waiver request in the event they are unable to meet the June deadline.***	Part D bid submission deadline
423.401(a)(1)	Licensure
423.420	Solvency standards for non-licensed

Part D Regulation	**Regulatory Requirement(s) Description**
	entities
423.462	Medicare secondary payer procedures
423.464(c)	Coordination of benefits and user fees
423.464(f)(2) and 423.464(f)(4)	Coordination with other prescription drug coverage
423.502(b)(1)(i-ii)	Documentation of State licensure or Federal waiver
423.504(b)(2-3), 423.504(b)(4)(i-v) and (vi)(A-E), and 423.504(d) ***Note: Organizations are required to abide by 423.504(b)(4)(vi)(F-H), 423.504(b)(5), 423.504(c), and 423.504(e)***	Conditions necessary to contract as a Part D plan sponsor
423.505(a-c) and 423.505(e-i) ***Note: Organizations are required to abide by 423.505(d and j)***	Contract provisions
423.505(k)(6) ***Note: Organizations are required to abide by 423.505(k)(1-5)***	Certification for purposes of price compare
423.506(a)-(b) ***Note: Organizations are required to abide by 423.506(c)-(e)***	Effective date and term of contract
423.512 – 423.514	Contracting terms
423.551-423.552	Change of ownership or leasing of facilities during term of contract
423.560-423.638	Grievances, coverage determinations, and appeals
N/A	A PDP sponsor is required to be a nongovernmental entity