June 2016

ADAPTED PACE Protocol

Development of the ADAPTED PACE Protocol

The ADAPTED PACE protocol was developed by a work group with representatives from the disability and PACE communities. The protocol used the original On Lok PACE protocol as a starting point and adapted it to address the needs and concerns of people with disabilities. This process included input from disability community experts and references to standards and models that have been developed for disability services. The standards and models considered include the Home and Community Based Settings rule recently finalized by the Centers for Medicare and Medicaid Services, the Bazelon Center's Community Integration for People with Disabilities: Key Principles (May, 2014) and the IMPACT Act recently passed by Congress. While the protocol reflects the input, advice and consensus of the work group members, it does not represent any individual member organization's recommendations or policies.

ADAPTED PACE Protocol Work Group Members

American Association on Health and Disability
ANCOR
Autistic Self Advocacy Network
Lakeshore Foundation
Lutheran Services in America Disability Network
National Association of State Directors of Developmental Disability Services
National MS Society
National PACE Association

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Purpose of the ADAPTED PACE Protocol

The ADAPTED PACE protocol is an operational framework for a comprehensive, capitated and community-based service model, based on the PACE program. The protocol is designed to support the highest quality of life and quality of care for the subset of individuals with a disability who also have complex medical care needs. These individuals include those with a physical, intellectual or developmental, cognitive or behavioral health related disability. In addition to the individual's disability, the individual who would be served by an ADAPTED PACE program will have a complex medical need.

The protocol identifies two criteria by which a complex medical need may be determined by one or more of the following criteria:

- certification by the state of the need for a nursing home level of care; or
- presence of a chronic disease or medical condition that is expected to last for more than 1 year, limits what a person can do, and requires ongoing medical monitoring; in addition, need for human assistance with two or more activities of daily living (ADLs), and either:

  (a) a non-elective hospital admission within the last 12 months, with use of acute or sub-acute rehabilitation services within the last 12 months; or
  (b) evidence of a need for ongoing medical management of complex systems to promote health and safety and reduce comorbid complications; with, an assessment indicating need for functional support e.g. an Expanded Disability Status Scale (EDSS) score of 7.5 and above or other comparable assessment.

The protocol is designed to balance person-centered planning that supports community living with the ability for the ADAPTED PACE provider to integrate care while bearing risk for the outcomes and cost of care. The protocol aims to find this balance by including robust and enforceable protections for PACE participants while supporting ADAPTED PACE providers in offering a full array of service settings, coordinated by an active interdisciplinary team, in developing care plan options. As part of achieving these ends, all references to person-centered planning used throughout this document mean person-centered planning that complies with the requirements laid out in 45 CFR 441.301(c)(1-3).

Section 1: Overview

Approximately 62 million Americans experience some level of physical, cognitive, sensory or emotional impairment. Many of these individuals are able to find the supports and services they need in order to experience a high quality of life and independence. Notwithstanding the opportunities available to people with disabilities as a result of these services and supports, there are significant challenges facing people with disabilities. It is estimated that for 30 million people their level of impairment is significant enough to inhibit their ability to participate in society, maintain a household, work, or engage in activities and hobbies. [i]

The current delivery system is ill-equipped to meet the needs of these individuals, who as a result face physical, social and attitudinal barriers to quality health care. For example:

- 31% of individuals with disabilities rank their health as fair or poor, compared to 7% of people without a disability.[ii]
- Individuals with disabilities are at far greater risk for chronic diseases such as diabetes, HIV/AIDs and depression. [iii]
- Individuals with disabilities experience higher incidences of unhealthy behaviors, including obesity, sedentary lifestyle, cigarette use, and substance abuse. [iv]
- People with serious mental illness (SMI) are dying 25 years earlier than the general population.[v]
- Women with disabilities experience significant physical and attitudinal barriers to routine gynecologic and reproductive health care. According to one study, women with disabilities were 24 percent less likely to have received a Pap test during the previous year than women without disabilities and were nearly three times more likely than women without disabilities to have postponed needed medical care.[vi]

Provider-Led Care Models

Existing care models – especially large-scale, insurance based plans, do not offer the customized, integrated benefits sometimes required by individuals with disabilities. However, integrated delivery models hold the promise of improving quality of life and quality of care for all individuals, including individuals with disabilities. Provider-led models are especially well positioned to offer the individually-tailored, intensive, highly integrated care necessary to better serve vulnerable populations. Distinct from insurance based models, provider-led care models allow providers to directly accept responsibility for the delivery, coordination and cost of care for their patients, without having to work through insurers for utilization management, coverage determinations, or payment.

The Program of All-Inclusive Care for the Elderly (PACE) model is a provider based care model that successfully integrates health care and long term services and supports for frail, elderly individuals. PACE offers primary and specialty medical care, in-home services, prescription drugs, physical and occupational therapy, day services, social work, and other benefits. By integrating the full range of services an individual needs, PACE can help nursing home eligible individuals remain in their homes and communities, avoid costly hospitalizations, emergency room visits, and nursing home placements.

ADAPTED PACE

Consideration of a pilot to test the expansion and adaptation of the PACE model (ADAPTED PACE) to serve new populations was recently made possible by the PACE Innovation Act which granted waiver authority to the Center for Medicare and Medicaid Services for this purpose. A pilot would allow ADAPTED PACE to serve new populations, including older adults who are at-risk for requiring a nursing home level of care, as well as younger individuals with physical disabilities, individuals with intellectual or developmental disabilities, individuals with mental illness, and others with complex care needs. The recommended core elements of an ADAPTED PACE pilot are:

- **Person-centered services** – that reflect individual goals, priorities and situations
- **Functional independence** – care planning focuses on prevention and supporting consumers in optimizing their physical and mental health and functional independence

- **Comprehensive benefits** – that includes all medical, social and supportive services
- **Interdisciplinary teams** – that assess needs, and plan and deliver health care and LTSS
- **Intensive community based care** –that serves individuals in their homes and communities
- **Capitated financing** – that combines Medicare, Medicaid and private financing
- **Rigorous quality standards and performance measures** – that assess and improve quality

The following document describes the essential features of the ADAPTED PACE demonstration, including provider requirements; participant rights; eligibility, enrollment, and disenrollment policies; service delivery; quality assurance; and other features.

Section 2: Provider Requirements

In general, ADAPTED PACE are provider-sponsored organizations that provide a full range of health care services and long-term services and supports. These organizations could be sponsored by an existing PACE organization, by an organization currently serving people with disabilities, or by a partnership of both kinds of organizations. Partnerships would offer the PACE organization the expertise of the disability service provider (e.g. Centers for Independent Living, SILCs, Councils on Developmental Disabilities, P&As, state APSE chapters) in understanding the needs of a person with a disability and establishing the full range of services and supports needed, as well as expertise in HCBS regulations. For disability providers, a partnership with PACE would offer the PACE organization's experience in managing a capitated, fully-integrated, and comprehensive delivery system. Distinct from insurance based models that contract with a broad array of disparate providers, in the ADAPTED PACE model, providers organize under a single corporate umbrella and assume responsibility and risk for delivering the full range of Medicare and Medicaid covered benefits. Below are essential requirements for providers seeking to offer services under an ADAPTED PACE model.

1) ADAPTED PACE organizations must include in their mission statement or philosophy the following values:
   a) To enhance the quality of life and autonomy for participants;
   b) To maximize dignity and respect of participants;
   c) To fully engage the individual in person-centered planning that addresses his or her needs, wants and priorities;
   d) To support participants' self-determination and dignity;
   e) To respect participants' right to be employed, if appropriate, have a place to call home and be engaged in the community with family and friends; and
   f) To preserve and support the participant's family unit.

2) Organizational Structure
   a) ADAPTED PACE organizations must meet one of the following organizational structures:
      i) A department, subsidiary or free-standing not-for-profit 501(c)(3) organization;
      ii) A department, subsidiary or free-standing for-profit corporation; or
      iii) A governmental or tribal entity at the city, county or state level.
   b) ADAPTED PACE organizations must establish a participant advisory committee to provide advice to the governing body on matters of concern to participants. Participants and representatives of participants must constitute a majority of the membership of this committee. The participant

advisory committee must provide the liaison to the governing body with meeting minutes that include participant issues.

c) The ADAPTED PACE provider must make available a current organizational chart displaying corporate officers and relationships to any part or other corporate subsidiaries or affiliates, and indicating the ADAPTED PACE provider's relationship to the corporate board.

3) Organizational Structure, Competencies and Capacity: The ADAPTED PACE provider shall have the administrative and service delivery ability to effectively organize and guide operations and meet the contractual obligations which include, but are not limited to:

a) Organizational Structure
   i) A policymaking body which oversees operations and devotes resources sufficient to effectively plan, organize, administer and evaluate the ADAPTED PACE provider's operation;
   ii) A Project Director whose responsibilities and duties are described in writing;
   iii) A Medical Director whose responsibilities and duties are defined in writing;
   iv) Demonstrated separation of medical, social and supportive services from fiscal and administrative management sufficient to assure that medical decisions will not be unduly influenced by fiscal and administrative management;
   v) Staff to maintain financial records and books of accounts on an accrual basis;
   vi) Staff to report data required for management, as well as the Federal and State governments;
   vii) Facilities and equipment that meet applicable State requirements; and
   viii) A system for informing employees and contract providers about all relevant provider requirements including coverage and appeal procedures.

b) Organizational Competency
   i) Competency, preferably demonstrated by experience of the sponsoring organization or its partner(s), in supporting person-centered planning to engage the participant in identifying his or her needs, and developing plans that meet those needs consistent with the participant's own quality of life and quality of care goals;
   ii) Competency, preferably demonstrated by experience of the sponsoring organization or its partner(s), in providing services and supports to individuals with disabilities inclusive of social supports; home and community-based services; long term services and supports; and primary, preventive and acute medical care; and
   iii) Competency, preferably demonstrated by experience of the sponsoring organization or its partner(s), in managing capitated budgets inclusive of applicable Medicare and Medicaid payment systems, financial risk management, network billing oversight and management, and maintenance of adequate financial risk reserves.

c) Service Capacity
   i) Ability to provide through its own staff in combination with a contracted network, the complete service package, including the full scope of Medicare and Medicaid benefits on a capitation basis regardless of the frequency, extent, or level of services provided to any participant; this includes but is not limited to:
      (1) Staff or contractual relationships to provide social supports, long term services and supports, and primary medical care; and
      (2) Ability to provide adapted and supported transportation.

ii) A standing multidisciplinary team composed of social, medical and health-related professionals and para-professionals, all of whom meet applicable state licensing and certification requirements and who provide direct care and services appropriate to participant need; and
iii) Ability to include certified peer providers as caregivers and as members of the PACE interdisciplinary team.

Section 3: Eligibility, Enrollment, Disenrollment

1) Eligibility
   a) ADAPTED PACE organizations seeking to participate in the demonstration must be able to serve one or more of the following categories of eligible individuals who have a disability, including but not limited to a physical, intellectual or developmental, cognitive or behavioral health related disability and who meet one or more of the following criteria:
      i) Are certified by the state to require a nursing home level of care;
      ii) Are certified by the state to require an intermediate care facility level of care and also have one or more chronic disease diagnoses; or
      iii) Have a chronic disease or medical condition that is expected to last for more than 1 year, limits what a person can do, and requires ongoing medical monitoring; these individuals must also need human assistance with two or more activities of daily living (ADLs), and either:
         (a) a non-elective hospital admission within the last 12 months, with use of acute or sub-acute rehabilitation services within the last 12 months; or
         (b) evidence of a need for ongoing medical management of complex systems to promote health and safety and reduce comorbid complications; with, an assessment indicating need for functional support e.g. an Expanded Disability Status Scale (EDSS) score of 7.5 and above or other comparable assessment.
   b) ADAPTED PACE organizations may choose not to enroll participants whose condition, at the point of enrollment is such that their health and safety would be jeopardized by remaining in their home and community.
   c) ADAPTED PACE organizations may limit eligibility to individuals who reside within a defined service area.

2) Pre-enrollment
   a) Prior to enrolling in an ADAPTED PACE program and at any time thereafter, prospective participants may request the support of a person-centered planning service to assist them in developing a plan with the ADAPTED PACE program's interdisciplinary team.
   b) At the direction of the prospective PACE participant, this support may include an independent assessment as well as participation in the ADAPTED PACE program's interdisciplinary team's pre-enrollment assessment and care planning process.
   c) Participants may also waive the independent assessment and person-centered planning service.
   d) Irrespective of the participant's use of a person-centered planning service, the ADAPTED PACE program is required to engage the participant in a needs assessment and care planning process that is person-centered, reflecting the participant's preferences and priorities with regard to achieving their highest possible quality of life and quality of care.

3) Enrollment
   a) Enrollment in the ADAPTED PACE program is voluntary.

b) Prior to enrollment, the prospective participant will be informed of the key features, care planning model, care delivery system and potential coverage limitations of the ADAPTED PACE program in order to make an informed decision regarding enrollment.
c) The participant must accept ADAPTED PACE as his/her care manager and its interdisciplinary team and their designees as his/her sole provider of services ("in-network" requirement); acceptance of this requirement does not waive the participant's right to utilize, throughout the participant's enrollment in the ADAPTED PACE program, an external person-centered planning service for the purpose of obtaining an independent needs assessment or of being represented by the service in the ADAPTED PACE program's interdisciplinary team's assessment and care planning activities; this right notwithstanding, the ADAPTED PACE organization will have the sole responsibility and authority for completing its own assessment, establishing the care plan and delivering, through its own or contracted network, the services required in order to implement the care plan.
d) Following referral to the program, ADAPTED PACE staff must schedule a screening visit with the potential participant and/or legal guardians to explain:
    i) The ADAPTED PACE program;
    ii) The "in-network" requirement;
    iii) The role of an independent person-centered planning service; and
    iv) Monthly fees, if any.
e) Following this explanation, the potential participant must sign a release of his/her medical and financial information.
f) The potential participant is assessed by the ADAPTED PACE provider to determine eligibility.
g) All participants, including Medicare-only eligibles, shall be reviewed by the State Medicaid agency for a one-time only certification at enrollment that the participant meets program eligibility requirements.
h) If the potential participant is eligible and is willing to join ADAPTED PACE, he/she must sign an Enrollment Agreement which contains the following information:
    i) Applicant's name, sex, date of birth, health insurance claim numbers, Medicare eligibility status (Part A and/or Part B) and number, Medicaid number or none;
    ii) Description of benefits available, including all Medicare and Medicaid covered services, and how services are allocated or can be obtained from ADAPTED PACE providers;
    iii) Explanation of participant premiums and procedures for payment, if any;
    iv) Effective date of enrollment;
    v) Explanation of participant rights, including the right to use an independent person-centered care planning service and the limitations on the role that service will play with regard to the ADAPTED PACE program (see Section 3, 3.b above), grievance procedures, conditions for enrollment and disenrollment and Medicare and Medicaid contacts in appeal situations;
    vi) Participant's obligation to notify ADAPTED PACE provider of a move or absence from the provider's service area;
    vii) Explanation of the "in-network" requirements and an acknowledgment on the part of the applicant that he/she understands that all services must be received through the ADAPTED PACE provider and their designees;
    viii) Explanation of procedures for obtaining emergency services and urgent care;
    ix) Requirement to maintain their own Medicare and Medicaid eligibility including Medicare Part B eligibility through the payment of required premiums;
    x) Statement that the private premium can only be raised once a year;
    xi) Explanation that the Medicare member may not disenroll from ADAPTED PACE at a Social Security office;

xii) Explanation that enrollment in ADAPTED PACE will result in automatic disenrollment from any other Medicare or Medicaid prepayment health plan;
xiii) Applicant's authorization for the disclosure and exchange of information between CMS, its agent, the State Medicaid agency and the ADAPTED PACE provider; and
xiv) Applicant's signature and date.

i) The participant's enrollment in the program is effective the first day of the calendar month following the signing date of the Enrollment Agreement.
j) Once the participant signs the Enrollment Agreement, he/she is given:
   i) A copy of the Enrollment Agreement;
   ii) The Member Handbook (Combined Contract and Evidence of Coverage), if different from the Enrollment Agreement;
   iii) A membership card;
   iv) An emergency sticker to be posted in his/her home in case of emergency; and
   v) A sticker for his/her Medicare card and, if applicable, a Medicaid card which indicates that he/she is a ADAPTED PACE participant.
k) Enrollment continues as long as desired by the participant, regardless of changes in health status, until death, voluntary disenrollment, or involuntary disenrollment as described in Section three.

4) Disenrollment
   a) An ADAPTED PACE participant may either voluntarily or involuntarily disenroll from the program at any time.
   b) A participant may be involuntarily disenrolled if she/he:
      i) Moves out of the program service area;
      ii) Is a person with decision making capacity who consistently does not comply with his/her individual plan of care and as a result
         (1) poses a significant risk to him/herself with potential for harm beyond the acknowledged risks agreed upon in a person-centered care planning process: or
         (2) poses a significant risk to others, including employees or contracted providers and professionals of the ADAPTED PACE program or others;
      iii) Experiences a breakdown in the physician and/or team-participant relationship such that the provider's ability to furnish services to either the participant or other participants is seriously impaired;
      iv) Refuses services and/or is unwilling to meet conditions of enrollment as they appear in the Enrollment Agreement;
      v) Refuses to provide accurate financial information, provides false information or illegally transfers assets;
      vi) Fails to pay or to make satisfactory arrangements to pay any amount due the provider after a 30-day grace-period;
      vii) Is out of the service area for more than 30 continuous days (unless other arrangements have been made); or
      viii) Is enrolled in a program that loses its contracts and/or licenses enabling it to offer health care services.
   c) For voluntary disenrollments, the ADAPTED PACE provider shall use the most expedient process allowed for by Medicare and Medicaid procedures while ensuring a coordinated disenrollment date.
      i) The ADAPTED PACE provider disenrollment procedures should be included in the contracts with CMS and the state Medicaid agency.

ii) These contracts should specify that ADAPTED PACE participants retain their position in any waiting lists maintained by the state Medicaid program for accessing services that would in whole or in part substitute for the services provided by the ADAPTED PACE program.
iii) These contracts should specify that ADAPTED PACE participants can return to Medicaid program services they were using prior to enrollment in the ADAPTED PACE program.
iv) Until enrollment is terminated, ADAPTED PACE participants are required to continue using the ADAPTED PACE provider services and remain liable for any premiums. The ADAPTED PACE provider shall continue to provide all needed services until the date of termination.

d) To facilitate a participant's reinstatement in the fee-for-service or managed care system, the PACE provider must:
   i) Assist a participant who wished to return to the system by making appropriate referrals and by making medical records available to new providers, and
   ii) Work with CMS and the State Medicaid agency to reinstate his/her benefits in the system.
e) Renewal provisions
   i) If the reason for disenrollment is due to failure to pay, payment of the monthly fee before the end of the month of disenrollment will result in reinstatement as of the first day of succeeding month.
   ii) In the case of a voluntary disenrollment, a one-time only reinstatement will be allowed if the participant meets eligibility criteria.

   All voluntary and involuntary disenrollments must be documented and available for review by CMS and the State Medicaid agency.

Section 4: Participant Rights

The ADAPTED PACE provider has a formal Participant Bill of Rights designed to protect and promote the rights of each participant to be treated with dignity and respect.

1) These rights, which may be exercised by the participant or his/her representative, if necessary, include the rights:
   a) To have the "Enrollment Agreement" fully discussed and explained;
   b) To be fully informed in writing prior to and at the time of enrollment (as well as during participating) of the services available from the ADAPTED PACE provider;
   c) To be fully informed of rights and responsibilities as a participant and/or all rules and regulations governing participation;
   d) To be encouraged and assisted to exercise rights as a participant, as well as civil and legal rights;
   e) To be encouraged and assisted to voice grievances and recommend changes in policies and services to ADAPTED PACE staff and outside representatives of his/her choice. There will be no restraint, interference, coercion, discrimination or reprisal by the ADAPTED PACE staff towards participants exercising this right;
   f) To be fully informed by the interdisciplinary team of health and functional status;
   g) To lead the development and implementation of the person-centered care plan where possible;
   h) To access an external, independent person-centered planning service designated by the state and contracted by the ADAPTED PACE organization. Through this service, the participant can obtain a person centered planning advocate to participate as a member of the ADAPTED PACE interdisciplinary team for the purpose of promoting and assuring that the care plan is developed in accordance with the person-centered planning requirements of the HCBS rule codified at 45 CFR 441.301;
   i) To decline the services of an external, independent person center care plan service;

j) To receive social and long term services and supports;
k) To receive treatment, habilitative, and rehabilitative services;
l) To have dignity, privacy, and humane care;
m) To be free from harm, including unnecessary physical restraint or isolation, excessive medication, physical or mental abuse or neglect;
n) To be free from hazardous procedures;
o) To have control over their own day, including any employment, educational or leisure activities they pursue;
p) To be given reasonable advance notice of any transfer to another part of the program for medical reasons or for the participant's welfare or that of other participants. Such actions will be documented in the health record;
q) To be assured of confidential treatment of all information contained in the health record, including information contained in any automated data bank. Written consent is required for the release of information to persons not otherwise authorized under law to receive it. Participants may provide written consent which limits the degree of information and the persons to whom information may be given;
r) To refuse treatment and be informed of the consequences of such refusal;
s) To dis-enroll from the program at any time subject to the terms of this agreement; and
t) To establish advance directives and make health care decisions.

2) Written policies or established procedures identify mechanisms for ensuring that the participant and family members understand their rights including items listed above.
   a) Staff must orally review the Participant Bill of Rights with the participant and family at enrollment in a language understood by the participant. A copy of the Bill of Rights is included in the member handbook given to participants at enrollment.

3) Complaints, Grievances and Appeals
   The ADAPTED PACE provider must have internal procedures which provide participants and their family members a process for expressing dissatisfaction with the services provided by ADAPTED PACE and which allow for orderly resolution of any complaint or grievance. Furthermore, all involuntary disenrollments, other than those resulting from participants moving out of the ADAPTED PACE provider's geographic service area, are considered participant grievances and are subject to these procedures:
   a) The ADAPTED PACE provider must have written internal grievance procedures which describe the process by which participants can make appeals, and give the time frames for the ADAPTED PACE provider's response to participants.
   b) The ADAPTED PACE provider must inform all participants of the grievance procedures in writing (i.e., in member handbooks).
   c) In cases where grievances are not resolved to the participant's satisfaction (e.g., denial of payment for claim or refusal of services), the ADAPTED PACE provider must state the specific reasons for its determination and inform the participant of his/her right to appeal. The ADAPTED PACE provider must process grievances in a timely manner.
   d) Reconsideration of grievances must be made by a person or persons who were not involved in making the initial determination. The ADAPTED PACE provider must give the parties to the reconsideration reasonable opportunity to present evidence related to the issue in dispute, in person as well as in writing.

e) All determinations that are wholly or partially adverse to the participant must be forwarded to CMS and the State Medicaid agency. If on appeal a judgment is made in favor of the participant, the PACE provider must take appropriate action in a timely manner.

Section 5: Service Coverage and Delivery

Service Coverage: If a Medicare beneficiary or Medicaid recipient chooses to enroll in an ADAPTED PACE program, the following conditions apply:

1) The ADAPTED PACE benefit package for all participants, regardless of the source of payment, must include the following:
   a) All Medicare-covered items and services;
   b) All Medicaid-covered items and services;
   c) Other services determined necessary by the interdisciplinary team to improve and maintain the participant's overall health, functional status, dignity, and quality of life; and
   d) Medicare and Medicaid benefit limitations and conditions relating to amount, duration, scope of services, deductibles, copayments, coinsurance or other cost-sharing do not apply.

2) The ADAPTED PACE provider must provide its participants with access to social and long term supports and services, medical care and other services, as applicable, 24 hours per day, 7 days a week, 365 days per year.

3) At a minimum each ADAPTED PACE provider shall provide the following services:
   a) Multidisciplinary assessment as defined in section 4;
   b) Person-centered care planning as defined in section 5;
   c) Primary care services including physician and nursing services;
   d) Social work services;
   e) Habilitative, rehabilitative and restorative therapies, including physical therapy, occupational therapy, and speech and language therapy;
   f) Personal care and supportive services;
   g) Nutritional counseling;
   h) Recreational therapy;
   i) Transportation;
   j) Meals;
   k) Medical specialty services including, but not limited to: anesthesiology, audiology, cardiology, dentistry, dermatology, gastroenterology, gynecology, internal medicine, nephrology, neurology, neuropsychology, neurosurgery, oncology, ophthalmology, oral surgery, orthopedic surgery, otorhinolaryngology, plastic surgery, pharmacy consulting services, podiatry, physiatry, psychiatry, pulmonary disease, radiology, rheumatology, surgery, thoracic and vascular surgery, and urology;
   l) Laboratory tests, x-rays and other diagnostic procedures;
   m) Drugs and biologicals;
   n) Prosthetics, orthotics, and durable medical equipment, assistive devices and assistive technology, corrective vision devices such as eyeglasses and lenses, hearing aids, dentures, and repairs and maintenance for these items;
   o) Acute inpatient care:
      i) Ambulance;
      ii) Emergency room care and treatment room services;

iii) Semi-private room and board;
iv) General medical and nursing services;
v) Medical surgical/intensive care/coronary care unit, as necessary;
vi) Laboratory tests, x-rays and other diagnostic procedures;
vii) Drugs and biologicals;
viii) Blood and blood derivatives;
ix) Surgical care, including the use of anesthesia;
x) Use of oxygen;
xi) Physical, speech/language, occupational, and respiratory therapies;
xii) Direct personal supports as needed; and
xiii) Social services.

p) Nursing facility care:
i) Semi-private room and board;
ii) Physician and skilled nursing services;
iii) Custodial care;
iv) Personal care and assistance;
v) Drugs and biologicals;
vi) Physical, speech/language, occupational, and recreational therapies, if necessary;
vii) Social services; and
viii) Medical supplies and appliances.

q) Employment services and supports;

r) Supports and services that support individuals' ability to secure and maintain community-based housing; and

s) Additional services determined necessary by the multidisciplinary team.

4) Assessment

a) The following members of the multidisciplinary team shall conduct individual, in-person assessments of the participant's health and social status upon enrollment in the program and on a [biannual/annual] basis thereafter:
i) Primary Care physician;
ii) Nurse;
iii) Social Worker;
iv) Physical therapist and/or occupational therapist;
v) Certified peer providers; and
vi) Other disciplines, as determined by recommendation of the primary care provider, nurse, social worker, therapist, or as requested by the participant.

b) As part of that assessment, the team shall:
i) Conduct the assessment in consultation with the individual, and if applicable, the individual's authorized representative, and include the opportunity for the individual to identify other persons to be consulted, such as, but not limited to, the individuals' spouse, family, guardian, and existing care team.
ii) Examine the individual's relevant history including findings from the independent evaluation of eligibility, medical records, and objective evaluation of functional ability, and any other records or information needed to develop the participant-centered service plan identified below.
iii) Include in the assessment the individual's physical, cognitive and behavioral health care and support needs, strengths and preferences, available service and housing options, and if

unpaid caregivers will be relied upon to implement any elements of the participant-centered service plan, a caregiver assessment.

c) When the health status or psycho-social situation of a participant changes, he/she is reassessed by the team or by select members of the team to develop a new treatment plan.

5) Emergency Care: Emergency services are defined as covered inpatient or outpatient services that are furnished in or out of the ADAPTED PACE provider's service area by a source other than the PACE provider or its contract providers and:
   a) Are needed immediately because of an injury or sudden illness; and
   b) The time required to reach the ADAPTED PACE provider staff and/or contract providers would have meant risk of permanent damage to the participant's heath.

6) Urgent Care: Urgently needed services are covered services required in order to prevent a serious deterioration of a participant's health that results from an unforeseen illness or injury if:
   a) The participant is temporarily absent from the provider's service area; and
   b) The receipt of health care services cannot be delayed until the participant returns to the provider's service area.

7) Excluded services are:
   a) Any service which has not been authorized by the multidisciplinary team, even if it is listed as a covered benefit;
   b) Services rendered in a non-emergency setting or for a non-emergency reason without authorization;
   c) Prescription and over-the-counter drugs not prescribed by the ADAPTED PACE provider physician;
   d) In inpatient facilities, private room and private duty nursing, unless medically necessary, and non-medical items for personal convenience such as telephone charges, radio or television rental;
   e) Cosmetic surgery unless required for improved functioning of a malformed part of the body resulting from an accidental injury or for reconstruction following mastectomy;
   f) Experimental medical, surgical or other health procedures or procedures not generally available;
   g) Care in a government hospital (VA, federal/State hospital) unless authorized;
   h) Service in any county hospital for the treatment of tuberculosis or chronic, medically-uncomplicated drug dependency or alcoholism; and
   i) Any services rendered outside of the United States.

Service Delivery:

1) ADAPTED PACE is a comprehensive health and social services delivery system which integrates acute and long-term services and supports. The ADAPTED PACE program provides these services in all settings, which may include, but are not limited to, the participant's home, community-based settings, outpatient facilities, and inpatient facilities.

2) ADAPTED PACE Center:
   ADAPTED PACE programs are permitted, **but not required**, to establish ADAPTED PACE centers for coordination and provision of many services.
   a) Any HCBS provided under ADAPTED PACE must comply with the HCBS Rule at 45 CFR 441.301, except for personal-care services furnished for the purpose of accessing services of the center
   b) Services furnished at ADAPTED PACE centers may include, but are not limited to:

i) Primary care, including physician and nursing services;
ii) Restorative therapies, including physical therapy, speech and language therapy and occupational therapy, specialized seating and mobility services;
iii) Personal care and supportive services as accommodations or adaptations to access the services of the center;
iv) Nutritional counseling; and
v) Meals.

3) The following ADAPTED PACE services must be provided in a setting that complies with the HCBS settings rule codified at 45 CFR 441.301(c)(4-5):
   a) Person-centered care planning as defined in section 5,
   b) Social work services,
   c) Personal care and supportive services,
   d) Recreational therapy,
   e) Transportation,
   f) Meals,
   g) Employment services and supports, and
   h) Supports and services that support individuals' ability to secure and maintain community-based housing.

4) Attendance at the center is determined by the participant, in coordination with the interdisciplinary team, based on individual preferences and needs.
   a) Individuals who choose not to receive services at the ADAPTED PACE center, or who chose to receive services that are not eligible for provision at the ADAPTED PACE Center, must be able to access services in other settings that:
      i) Are integrated in and support full access of participants to the greater community, including opportunities to seek employment and work in competitive integrated settings, engage in community life, control personal resources, and receive services in the community.
      ii) Are selected by the individual from among setting options including non-disability specific settings and options for a private unit in a residential setting. The setting options are identified and documented in the participant-centered service plan and are based on an individual's needs, preferences, and for residential settings, resources available for room and board.
      iii) Ensure an individual's rights of privacy, dignity and respect, and freedom from coercion and restraint.
      iv) Optimizes, but does not regiment, individual initiative, autonomy, and independence in making life choices, including but not limited to daily activities, physical environment and with whom to interact.
      v) Comply with the qualities and requirements of an HCBS setting laid out in 45 CFR 441.301(c)(4-5) including guidelines around person-centered planning and participant choice.

5) Interdisciplinary team:
   The effective delivery of services depends on a consistent multidisciplinary team whose members are knowledgeable of individual participant's needs. Each participant is assigned to an inter-disciplinary team of staff and contract professionals which maintains responsibility for assessment, treatment planning, and care delivery and coordination on a 24-hour basis. Each participant is assigned a core team of the following members:

a) Primary Care Physician;
b) Nurse;
c) Social Worker;
d) Physical and/or Occupational Therapist; and
e) Additional team members, as determined by the core-team, in conjunction with the participant, including:
    i) A physical therapist (in the case of a core interdisciplinary team with an occupational therapist as a member);
    ii) An occupational therapist (in the case of a core interdisciplinary team with a physical therapist as a member);
    iii) A speech or language therapist where a participant has a documented communication impairment;
    iv) A recreational therapist, activity therapist or activity coordinator;
    v) A dietician;
    vi) A home care coordinator;
    vii) A personal care attendant or representative;
    viii) A certified peer provider, if used by the participant;
    ix) A driver or representative;
    x) An employment counselor;
    xi) Such other professionals as may be periodically designated by the members of the core interdisciplinary team to meet the unique needs of that individual. e.g. a neurologist, psychiatrist/psychologist; or
    xii) Person centered planning advocate as determined by the participant.

6) The interdisciplinary team authorizes ADAPTED PACE covered services which meet the specific needs of the participant.

7) Ultimate responsibility for management of medical situations rests with the ADAPTED PACE primary care physician. The physician keeps the multidisciplinary team informed of the medical condition of each participant and remains alert to pertinent input from other team members.

8) The team implements the treatment plan by providing services directly and supervising the delivery of services provided by contract providers.

9) The participant's health status and psycho-social conditions as well as the effectiveness of the treatment plan are monitored continuously through direct provision of services, informal observation, input from participants and their representatives, and communications among members of the multidisciplinary team and other providers.

10) Self-Directed Personal Care
    a) ADAPTED PACE programs shall allow participants to self-direct the furnishing of certain personal care attendant services.
    b) Such participants may select a personal care attendant to furnish such services in consultation with the ADAPTED PACE provider.
    c) Personal attendants shall have appropriate training but are not required to be a member of the ADAPTED PACE staff.

11) The ADAPTED PACE provider must ensure accessible and adequate service capacity to meet the needs of the enrolled population. As enrollment increases, the number of multidisciplinary teams and other ADAPTED PACE services must increase accordingly.

12) Primary medical care is provided by an ADAPTED PACE approved primary care physician. The primary care physician approves the participant's use of medical specialists and inpatient care and is an integral member of the multidisciplinary team.

13) Since ADAPTED PACE services may be provided in the home, the coordination of in-home services with ADAPTED PACE center and primary care services is critical to effective service delivery. The ADAPTED PACE provider shall designate a home care liaison to supervise and coordinate home care services whether these services are provided directly by the provider or through a contract vendor.

14) All other PACE covered services can be provided either directly or on a contractual basis with related or unrelated organizations, agencies, or providers.

15) Medical Records
    a) To facilitate continuity of care, the ADAPTED PACE provider must maintain a single comprehensive medical record for each participant which contains:
        i) Appropriate identifying information;
        ii) Documentation of all services provided;
        iii) Multidisciplinary assessments, reassessments, plans of care, treatment and progress notes, signed and dated;
        iv) Lab reports;
        v) Medications record;
        vi) Hospital discharge summaries;
        vii) Reports from contracted providers;
        viii) Contacts with informal support;
        ix) Enrollment Agreements;
        x) Physician orders;
        xi) Discharge summary and disenrollment agreement, if applicable;
        xii) Information on advance directives; and
        xiii) Disclosure of release of information.
    b) Chart organization and documentation shall meet professional and other applicable requirements.
    c) Electronic health records should be consistent with applicable interoperability standards and where possible compatible with standardized formats and templates as applied to other medical care and long term service and support settings (e.g. SNFs, home health).
    d) Policies to ensure confidentiality, storage and retention must be in place in accordance with professional and other applicable requirements.

Section 6: Quality Assurance

1) The ADAPTED PACE multidisciplinary team is a critical element of quality assurance. The process of service delivery in this model requires the team to identify participant problems, determine appropriate treatment objectives, select interventions and evaluate efficiencies of care on an individual participant basis. This activity becomes the foundation for all subsequent quality

assurance activities.

2) The ADAPTED PACE provider must have a written plan of Quality Assurance and Improvement which provides for a system of ongoing assessment, implementation, evaluation, and revision of activities related to overall program administration and services. The plan should include, at the minimum, the following essential elements:
   a) Standards that are performance benchmarks, established by the provider, and are incorporated into the provider Policy and Procedure Manual. The provider standards must be based on the ADAPTED PACE protocol, applicable standards and applicable licensing and certification criteria.
   b) Goals and objectives that provide a framework for quality improvement activities, evaluation and corrective action. These goals and objectives will be reviewed periodically.
   c) Quality indicators that are objective and measurable variables related to the entire range of services provided by the ADAPTED PACE provider. The methodology should assure that all demographic groups, all care settings will be included in the scope of the quality assurance review.
   d) Quality indicators should be selected for review on the basis of high volume, high risk diagnosis or procedure, adverse outcomes, or some other problem-focused method consistent with the state of the art.
   e) Process to review the effectiveness of the ADAPTED PACE multidisciplinary team in its ability to assess participant's care needs, identify the participant's treatment goals, assess effectiveness of interventions, evaluate adequacy and appropriateness of service utilization and reorganize plan as necessary.
   f) Policies and procedures related to establishing committees with community input to (1) evaluate data collected pertaining to quality indicators, (2) address the process and outcomes of the quality improvement plan, and (3) provide input related to ethical decision making including end-of-life issues and implementation of the Patient Self-Determination Act (PSDA).
      i) These procedures will define a process for taking appropriate action to resolve problems identified as part the quality assurance activities.
      ii) Policies will be established that define professional qualifications of individuals participating on these committees.
   g) Participant involvement in program QA plan and evaluation of satisfaction with services.
   h) Board level accountability for overall oversight of program activities and review of the QA plan, annual review and approval of the quality assurance plan by the program board with periodic feedback to Board on review process by oversight committees.
   i) The ADAPTED PACE provider shall designate an individual to coordinate and oversee implementation of quality assurance activities.

Section 7: Quality Measurement

   a) ADAPTED PACE providers will specify a set or subset of **National Quality Forum** "endorsed measures" for public reporting in the following measure categories: care coordination, health-and-well-being, person-and-family-centered, home-and-community-based services and supports (under development; none are yet considered), and persons dually eligible for Medicare and Medicaid.
   b) ADAPTED PACE providers will specify a set or subset of Beneficiary Choice and Control measures for public reporting drawing from the **National Core Indicators** (NASDDDS & HSRI; modified by NASUAD-NASDDDS-HSRI) and **Personal Outcome Measures** (Council of Quality and Leadership).

c) ADAPTED PACE providers will specify a set or subset of **CAHPS measures** for public reporting utilizing the instrument modified by the **Westchester Institute for Human Development (NY)** (ACL-NIDILRR funded) research and adaptation of **CAHPS (Consumer Assessment of Healthcare Providers and Systems)** for persons with intellectual disability.

Section 8: Provider Administration

1) Contracting Requirements
    a. Subcontracts between the ADAPTED PACE provider and contract providers shall be established for services not delivered directly by the ADAPTED PACE provider.
        i. The ADAPTED PACE provider may contract only with qualified or licensed providers, who meet Federal and State requirements as applicable;
        ii. Contract providers must be accessible to participants, located either within or near the ADAPTED PACE provider's geographic catchment area;
        iii. The format of subcontracts must be approved by CMS and the State Medicaid agency;
        iv. A list of subcontractors must be on file at the State Medicaid agency and updated as it changes; and
        v. Copies of signed contracts for inpatient care are included in the contract between the ADAPTED PACE provider, CMS, and the State Medicaid agency.
    b. Each subcontract shall contain:
        i. Name of subcontractor;
        ii. Specification of the services provided;
        iii. Specification of reimbursement rate and payment method;
        iv. Specification of the terms of the subcontract, including the beginning and ending dates, as well as methods of extension, re-negotiation and termination;
        v. Subcontractor agreement to provide services in accordance with the services authorized by the ADAPTED PACE multidisciplinary team;
        vi. Specification that the subcontract shall be governed by and construed in accordance with all laws, regulations and contractual obligations incumbent upon the ADAPTED PACE provider;
        vii. Subcontractor agreement to accept the ADAPTED PACE provider's payment as payment in full and not to bill participants, CMS, the State Medicaid agency or private insurers;
        viii. Subcontractor's agreement to hold harmless CMS, the State and ADAPTED PACE participants in the event that the ADAPTED PACE provider cannot or will not pay for services performed by the subcontractor pursuant to the subcontract;
        ix. Subcontractor's agreement that assignment or delegation of the subcontract is prohibited unless prior written approval is obtained from the ADAPTED PACE provider;
        x. Subcontractor's agreement to submit reports as required by the ADAPTED PACE provider; and
        xi. Subcontractor's agreement to make all books and records, pertaining to the goods and services furnished under the terms of the subcontract, available for inspection, examination or copying by the State Medicaid agency and/or CMS.

2) Data Collection and Reporting
    a. During the trial period, the ADAPTED PACE provider shall meet the following data collection and reporting requirements.
        i. The ADAPTED PACE provider is required to collect a standardized set of data which includes the following:
            1. Participant-specific intake, assessment and service utilization data, coded according to the guidelines in the ADAPTED PACE Data Collection Manual. The definition of data and the manner in which it is collected may be changed to meet changes in CMS and State Medicaid agency reporting requirements, in response to requests from ADAPTED PACE providers and other. Any changes made in data collection will incorporate sufficient lead time necessary to minimize transaction difficulty. Data uniformity shall be maintained across all ADAPTED PACE providers.
            2. Fiscal data based on cost center accounting structure provided by CMS and the State Medicaid agency. At the twelfth month, the year-to-date summary will provide the necessary annual data.
    b. At a minimum, the provider must maintain complete participant-specific utilization data on-site updated to one month prior to the present. Data shall be transmitted to CMS or its agent.
    c. To ensure the quality of the data, CMS or its agent may provide the ADAPTED PACE provider with training in the use of data collection tools and may conduct ongoing monitoring to determine data completeness and reliability. Data collection problems that are identified must be reported to CMS and the State Medicaid agency. If CMS and the State Medicaid agency determine that problems require correction, the ADAPTED PACE provider will be required to resolve them.
    d. CMS, or its agent, reserves the right to review and assure the reliability and completeness of data and may obtain all provider data for the purposes of program monitoring.
    e. The ADAPTED PACE provider will submit to CMS and State Medicaid agency, 45 days after the end of each quarter, the following quarterly reports:
        i. Quarterly narrative progress report; and
        ii. Quarterly program statistical reports – Program Status Report, Sociodemographic Characteristics of Participants, Health and Functional Status of Participants, and Service Utilization Summary. The contents of these reports may be changed to meet changes in Federal and State reporting requirements or for the purpose of program monitoring.
    f. For providers that have completed the trial period, CMS and its agent will work with ADAPTED PACE providers and their respective State Medicaid agencies to develop a standardized set of data to be collected by ADAPTED PACE providers and a standardized reporting process. To assure the quality of the data, requirements described above will apply.

3) Financial Reporting:
    a. For sites in the trial period, the following financial reports are required:
        i. The ADAPTED PACE provider will submit a Budgeted versus Actual Financial Report for the current and year-to-date periods to CMS, its agent, and the State Medicaid agency.

During the first year of operation, this report will be submitted on a monthly basis 45 days after the end of each month. Thereafter, this report will be submitted on a quarterly basis 45 days after the end of each quarter. CMS and the State Medicaid agency reserve the right to extend the submission of this report on a monthly basis should provider performance indicate a need for more frequent monitoring.

ii. The ADAPTED PACE provider must submit a cumulative cost report in the form and detail prescribed by CMS. The interim cost report is due 45 days after the end of each provider's fiscal quarter and covers the period from the beginning of the fiscal year through the respective quarter.

iii. The ADAPTED PACE provider must submit to CMS and the State Medicaid agency an independently certified cost report in the form and detail prescribed by CMS, no later than 180 days after the end of the provider's fiscal year.

iv. ADAPTED PACE providers which are separate corporate entities must submit to CMS and the State Medicaid agency a quarterly balance sheet.

b. For providers that have completed the trial period, CMS and its agent will work with ADAPTED PACE providers and their respective State Medicaid agencies to develop a standardized financial reporting process.

4) Maintenance of Books and Records

a. The ADAPTED PACE provider must establish policies and procedures for maintaining all books and records necessary to determine whether contractual obligations are met. Books include, but are not limited to:

i. Financial records,

ii. Medical records, and

iii. Personnel records.

b. Books and records must be made available to CMS and the State Medicaid agency upon request.

c. Records must be stored so as to be protected against loss, destruction or unauthorized use.

Section 9: External Oversight

1) General

It is the duty and responsibility of the Secretary to assure that requirements which govern the provision of care by ADAPTED PACE providers, and the enforcement of such requirements, are adequate to protect the health, safety, welfare, and rights of participants and to promote the effective and efficient use of public moneys. External oversight activities will include:

a. Periodic review of the financial status of the ADAPTED PACE provider to ensure its solvency and continuing viability; and

b. A periodic on-site survey, as described below, to determine the quality of care provided by the ADAPTED PACE provider and adherence to requirements defined in the contracts between the ADAPTED PACE provider, CMS and the State Medicaid agency.

2) National Standards and Surveys

ADAPTED PACE providers will be required to adhere to national standards. These standards will be established to be consistent with:

a. ADAPTED PACE Protocol – the standards will be consistent with the requirements stated in this protocol and allow for the operation of the ADAPTED PACE provider in a manner consistent with this protocol.
b. Home and Community Based Settings Standards – the standards will be consistent with the home and community based settings standards with exceptions as needed in order for the ADAPTED PACE provider to operate in a manner consistent with this ADAPTED PACE protocol. These exceptions include but are not limited to, that ADAPTED PACE providers be able, but not required, to operate a PACE center as a location in which social, rehabilitative, medical and supportive care may be provided as an option to the participant. This exception notwithstanding, the PACE Center may not be the only setting in which the services provided at the Center are made available to a participant.

3) CMS and its state administering agency partners will establish an on-site survey process for determining the quality of care provided by the ADAPTED PACE provider and the provider's adherence to contract requirements.
    a. The survey process will provide for surveys to be conducted at least once every two years by the State or through an accreditation organization or other entity. In addition, the Secretary will have the authority to conduct more frequent surveys, independently or in conjunction with the State, if there is reason to question the compliance of the ADAPTED PACE provider with any applicable requirements.
    b. The survey shall consist of an on-site visit which includes review of participant charts, interviews with staff and participants and observation of program operations including multidisciplinary team processes.
    c. The survey shall be performed by a team composed of individuals who are experienced in providing care to people with a disability and are knowledgeable about the PACE service delivery system. At a minimum, the team shall include a physician, nurse, social worker and a peer reviewer. The physician, nurse and social worker shall have experience in community-based care and should have recent care delivery experience. The peer reviewer shall be from a PACE provider serving people with a disability.
    d. Procedures will be established to determine whether corrective action has been taken by the PACE provider to resolve deficiencies identified during the survey.

Section 10: Provider Termination

1) The ADAPTED PACE provider can be terminated for any one of the following four reasons and in each case must comply with CMS and the State Medicaid agency guidelines for provider termination:
    a. Either CMS and/or the State Medicaid agency determine the provider cannot insure the health and safety of its participants. This determination may result from a medical survey or audit revealing provider deficiencies which CMS and/or the State determine cannot be corrected.
    b. The ADAPTED PACE provider chooses to discontinue providing services. In such event, a minimum of 90 days' notice must be given to CMS, its agent, and the State Medicaid agency regarding the provider's intent. Providers must give participants a minimum of 60 days notice.
    c. Either CMS and/or the State Medicaid agency can terminate the ADAPTED PACE provider's contract in response to large losses for which corrective action is unsuccessful. In response to financial audits which show a loss, the provider must

develop a plan which is designed to prevent future losses. If the plan is developed by the ADAPTED PACE provider and is determined to be unacceptable to CMS and the State Medicaid agency, the provider's contract may be terminated.

d. The provider may be terminated should it deviate from, violate or fail to comply with the contractual agreements of CMS and the State Medicaid agency.

2) The ADAPTED PACE provider is required to develop a detailed provider termination plan included in which are the following: the process of informing participants, the community, CMS and State Medicaid agency; and steps that will be taken to reinstate participants' Medicare and Medicaid benefits through the fee-for-service system, transition their care to other providers, and terminate the referral and intake process.

Section 11: Medicare and Medicaid Contracts Requirements

1) General
The ADAPTED PACE provider should have formal contracts in place with the responsible federal and state agencies, which incorporate the requirements defining and applicable to ADAPTED PACE providers. These legal requirements would be based upon the ADAPTED PACE Protocol. Absent such formal contracts the ADAPTED PACE Protocol and other requirements, if any, which the responsible agencies deem appropriate, would govern. Critical elements of the formal contract should include, but not be limited to, requirements related to:
   a. Organization of the ADAPTED PACE provider;
   b. Participant rights;
   c. Eligibility, enrollment and disenrollment policies;
   d. Service definition, coverage and arrangement;
   e. Quality assurance;
   f. Reimbursement;
   g. ADAPTED PACE provider administration; and
   h. ADAPTED PACE provider termination.

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[i] Altman, Barbara & A. Bernstein, Disability and Health in the United States, 2001-2005" (Hyattsville, MD: National Center for Health Statistics, 2008).

[ii] Seth Curtis and Dennis Heaphy, Disability Policy Consortium: Disabilities and Disparities: Executive Summary (March 2009).

[iii] *Ibid.*

[iv] *Ibid.*

[v] *See www.nasmhpd.org for Morbidity And Mortality In People With Serious Mental Illness report* (2006)

[vi] National Council on Disabilities "The Current State of Health Care for People with Disabilities." http://www.ncd.gov/publications/2009/Sept302009#Health%20Status