PACE Innovation Act Request for Information

Agency: Department of Health and Human Services
Centers for Medicare & Medicaid Services (CMS)

Type of Notice: Request for Information (RFI)

Summary: The Programs of All-Inclusive Care for the Elderly (PACE) provides comprehensive medical and social services to certain frail, community-dwelling elderly individuals, most of whom are dually eligible for Medicare and Medicaid benefits. An interdisciplinary team of health professionals works with PACE participants to coordinate care. For most participants, the comprehensive service package enables them to remain in the community rather than receive care in a nursing home. Financing for the program is capitated, which allows providers to deliver all services participants need, rather than only those reimbursable under Medicare and Medicaid fee-for-service.

The PACE Innovation Act of 2015 (PIA) provides authority to waive certain provisions of Section 1934 of the Social Security Act in order to test application of PACE-like models for additional populations, including populations under the age of 55 and those who do not qualify for a nursing home level of care, under Section 1115A of the Social Security Act. This Request for Information (RFI) has two parts.

In the first part, we seek comment on potential elements of a five-year PACE-like model test for individuals dually eligible for Medicare and Medicaid, age 21 and older, with disabilities that impair their mobility and who are assessed as requiring a nursing home level of care and meet other eligibility criteria. We have provisionally named this model "Person Centered Community Care" or P3C. This potential model is designed to meet the requirements of a model test under Section 1115A of the Social Security Act and to adapt the PACE model of care for one population of focus. In addition to feedback on the potential elements of the P3C model described below, we seek comment on the types of technical assistance that potential P3C organizations and states would require to participate in the model test.

In the second part of the RFI, we are seeking information on additional specific populations whose health outcomes could benefit from enrollment in PACE-like models, and how the PACE model of care could be adapted to better serve the needs of these populations and the currently eligible population.

CMS welcomes feedback on this RFI from all interested parties. Commenters should provide the name of their organization and a contact person, mailing address, email address, and phone number, and indicate whether the commenter is a current PACE organization, other provider type, state Medicaid agency, other state agency, provider or advocacy organization, or other entity. We expect to make the comments received under this RFI public; commenters should not include any proprietary information in their comments that they do not want made available to the public.

COMMENT DATE: To be assured consideration, comments must be received by 5 p.m. EST on February 10, 2017.

ADDRESS: Comments should be submitted electronically in pdf form to MMCOcapsmodel@cms.hhs.gov Please identify the organization or individual submitting comments in the title of the document.

FOR FURTHER INFORMATION CONTACT: paul.precht@cms.hhs.gov

Background: The President signed the PIA (PL 114-85) into law on November 5, 2015. The PIA authorizes the Secretary of Health and Human Services (HHS) to waive certain provisions of Section 1934 of the Social Security Act, which authorizes PACE under the Medicaid program, when designing and testing models under Section 1115A of the Social Security Act. Under the authority at Section 1115A of the Social Security Act, codified at 42 U.S.C. § 1315a, the Center for Medicare and Medicaid Innovation (Innovation Center) is authorized to "…test payment and service delivery models …to determine the effect of applying such models under [Medicare and Medicaid]." 42 U.S.C. § 1315a(b)(1). As modified by the PIA, Section 1115A of the Social Security Act includes the authority to waive applicable requirements of Sections 1934 and 1894 of the Social Security Act in order to conduct demonstration projects involving PACE.[1]

The PACE model of care has delivered integrated medical care and community supports to its population of focus—the frail elderly— helping enable participants to maintain their health, live at home and remain integrated into the community. Key elements of the PACE model of care include:

- Capitated payments for the delivery of all Medicare and Medicaid services;
- Provision and coordination of care, including development of a person-centered care plan for medical, behavioral, and social services, through an interdisciplinary team (IDT);
- Integration of all medical, behavioral, and social services to foster community living and community integration;
- Use of a PACE center to facilitate provision of medical care and social services, and to foster community integration; and
- Joint CMS-state program oversight.

The theory of action underlying any model test under the PIA is that adaptation of the PACE model of care will result in higher quality and more cost-effective care for beneficiaries that are the focus of the model.

Individuals with complex and chronic needs often have poor outcomes due to misalignment between Medicare and Medicaid services, which impacts continuity of care, mismanagement of medicine, length of stay in the community, high rates of potentially preventable hospitalizations

[1] As modified by the PIA, Section 1115A(d)(1) of the Social Security Act provides that CMS may not waive the requirements of Section 1934(b)(1)(A) of the Social Security Act (requiring PACE organizations to offer all items and services covered under Medicare and Medicaid without limitation), or section 1934(c)(5) of the Social Security Act (requiring PACE organizations to comply with certain requirements regarding enrollment and disenrollment).

and readmissions.[2] For individuals who are dually eligible, separate funding streams offer little incentive to deliver services efficiently.[3]

There is strong evidence that the PACE model of care is effective at reducing inpatient hospitalizations.[4] There is also evidence of higher rates of short-stay nursing facility admissions among PACE participants, but fewer long-stay nursing facility admissions.[5] In addition, there is some evidence of other positive quality effects from PACE for the management of specific health issues and for overall satisfaction with the program among participants.[6] Overall, evidence collected from PACE programs indicates improved outcomes for their population of focus, particularly the avoidance of inpatient admissions that impact the ability of individuals to live healthy lives in the community. While not directly applicable to the younger population that would be eligible for the P3C model, we believe the evidence of improved quality under PACE warrants testing an adaptation of this model of care for populations that have a similar need for coordination of health care and long term services and supports they now receive separately through Medicare and Medicaid.

The evidence for PACE's impact on Medicare and Medicaid costs is mixed. Some research shows no significant effect on Medicare costs,[7] while other analysis indicates the Medicare capitation rates result in increased Medicare spending.[8] The most rigorous research associates PACE with higher Medicaid costs, though it has shown the gap between PACE Medicaid capitation rates and Medicaid costs for a comparable population decreasing over time.[9] We believe that any potential for total cost increases under a PACE-like model can be substantially mitigated by the use of alternate rate setting methodologies for the Medicare and Medicaid capitated rates to ensure that the rates are less than otherwise would have been paid for a comparable population (see Section 1.c).

Part 1: Potential Elements of the P3C Model

The passage of the PIA followed two successive President's budget proposals requesting legislative authority to expand the PACE model of care to individuals with disabilities under the age of 55. In support of the proposed test of PACE to younger populations, CMS in cooperation

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[2] See Grabowski 2012 at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2690349/

[3] See Grabowski 2012 at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2690349/

[4] The evidence base for PACE's impact on quality and costs has been summarized in Evaluating PACE: a Review of the Literature (Ghosh, 2014), prepared for the U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. https://aspe.hhs.gov/sites/default/files/pdf/76976/PACELitRev.pdf

[5] See Ghosh, 205 at https://aspe.hhs.gov/basic-report/effect-pace-costs-nursing-home-admissions-and-mortality-2006-2011

[6] See Ghosh 2014 at: https://aspe.hhs.gov/sites/default/files/pdf/76976/PACELitRev.pdf

[7] See Ghosh, 2014, at https://aspe.hhs.gov/sites/default/files/pdf/76976/PACELitRev.pdf and MedPAC at http://medpac.gov/docs/default-source/reports/chapter-3-appendixes-care-coordination-programs-for-dual-eligible-beneficiaries-june-2012-report-.pdf?sfvrsn=0.http://medpac.gov/docs/default-source/reports/chapter-3-appendixes-care-coordination-programs-for-dual-eligible-beneficiaries-june-2012-report-.pdf?sfvrsn=0

[8] See MedPAC 2012 at: http://medpac.gov/docs/default-source/reports/chapter-3-appendixes-care-coordination-programs-for-dual-eligible-beneficiaries-june-2012-report-.pdf?sfvrsn=0

[9] See Ghosh, 2014, at https://aspe.hhs.gov/sites/default/files/pdf/76976/PACELitRev.pdf and MedPAC at http://medpac.gov/docs/default-source/reports/chapter-3-appendixes-care-coordination-programs-for-dual-eligible-beneficiaries-june-2012-report-.pdf?sfvrsn=0 .

with the Administration for Community Living (ACL), conducted extensive stakeholder outreach, including listening sessions in Philadelphia and Washington, DC, to learn the views of the disability community, including advocates and providers, on the applicability of the PACE model of care for people with disabilities. The results of this outreach work inform the potential P3C elements described in this RFI, in particular the need to adapt existing PACE requirements so that the P3C services support enhanced community integration for people with disabilities and offer a targeted, appropriate balance between medical care and the broader range of supports younger people with mobility-related disabilities may require to maximize independence.

CMS is now seeking feedback on specific aspects of a potential P3C model, which are described below. We note that the parameters of the P3C model described in this RFI may change, or CMS may ultimately decline to conduct the model test, at CMS' sole discretion. The information and questions in this RFI reflect ideas that CMS is considering, but it takes no position on whether any of the concepts or options discussed here or that may be raised by comments in response to this RFI would be feasible or permissible.

1.a Potential P3C Participant Eligibility

We are considering requiring that individuals enrolling in P3C organizations would need to meet the following eligibility criteria:

- Entitled to Medicare Part A and enrolled in Medicare Part B;
- Eligible for full Medicaid benefits;
- Assessed by the State Administering Agency (SAA) as requiring the level of care required under the state Medicaid plan for coverage of nursing facility services;
- Have one of the mobility-impairment related diagnoses listed in Appendix A;
- Have no third party insurance coverage;
- Be age 21 and over;
- Live in the P3C organization's service area; and,
- Be able, at the time of enrollment, to live in a community setting without jeopardy to health or safety.

Issues for Comment: We seek comment on the P3C participant eligibility criteria listed above. In particular, we request responses to the following questions:

- Certain P3C eligibility criteria listed above would be more restrictive than current PACE eligibility criteria, including the requirement for participants to be entitled to Medicare Part A and enrolled in Medicare Part B, eligible for full Medicaid benefits, and without third party coverage. We are considering limiting P3C to full benefit dual eligible individuals to ensure that P3C organizations would have an adequate Medicare and Medicaid payment stream to cover all services without charging participants a premium. The requirement not to have third party coverage is meant to facilitate analysis of the total cost of care under Section 1115A of the Social Security Act. Are these eligibility criteria appropriate for a test of the P3C model under Section 1115A of the Social Security Act?
- We are considering using the list of mobility-related diagnoses in Appendix A as an eligibility requirement to allow P3C organizations to tailor the model of care to the needs

of this population and to facilitate evaluation of the impacts and quality to a similar comparison group. Are the diagnoses listed in Appendix A appropriate for a P3C model focused on serving dually eligible beneficiaries with mobility impairments assessed as requiring a nursing home level of care? Should we include any additional diagnoses or conditions?

- We are considering limiting this model to individuals with mobility-related diagnoses, as outlined in Appendix A. Is it necessary to use specific diagnoses to limit eligibility or does the requirement to meet a nursing home level of care provide a sufficiently clinically similar population for development and implementation of a model of care and for evaluation of the model? What are the advantages and disadvantages of extending this model to a broader population of under-55 individuals who require a nursing home level of care? What challenges would we face extending the model to a broader population, and what additional safeguards would such a broader population require? Would a broader population make it easier or more difficult to include any innovations found successful in PACE?
- Our impetus for developing the P3C model has been to test an adaptation of the PACE model of care for younger dually eligible beneficiaries with mobility related disabilities and assessed as requiring a nursing home level of care who are currently ineligible for PACE, but the eligibility criteria described above do not include a maximum age for enrollment for a potential P3C model. As a result, individuals aged 55 or older who meet P3C eligibility criteria would also be eligible to enroll with existing PACE organizations. Does the overlap in P3C and current PACE eligibility raise issues of concern that should be addressed? What are the arguments for and against imposing a maximum eligibility age for the P3C model? In particular, we would be concerned that differing payment levels might incentivize organizations to shift participants between PACE and the P3C model. What protections and/or monitoring and corrective action strategies might be necessary to identify and prevent inappropriate shifting of participants?
- Would states seek flexibility in modifying eligibility criteria on a state-specific basis? If so, please explain how such modifications could affect the adaptations to the PACE model of care, changes to the PACE payment methodology described below, as well as the ability to evaluate the P3C model across states. As well, please address how the effect of any state-specific interventions on cost and quality would be evaluated.
- Note: we separately ask for comment on other potential populations elsewhere in this RFI.

1.b Potential Adaptations of the PACE Model of Care to Better Serve the P3C Population

The P3C model would likely retain many of the key elements of the PACE model of care, including:

- Full integration of long-term services and supports (LTSS), social and behavioral health services, preventive services, and all acute and episodic medical care, including prescription drug coverage;
- A robust IDT;
- A comprehensive and detailed person-centered assessment, care planning, and care coordination process;

- Fully capitated monthly Medicare and Medicaid payments.

However, consistent with PIA authority, we are considering that the P3C model could include a number of key differences from the PACE program, including:

- Programmatic flexibility to innovate on the PACE care model to provide greater freedom of provider choice, and enhanced focus on social and employment support services to support greater community integration;
- Changes necessary for appropriate care delivery to a mobility-impaired population that would allow P3C organizations to innovate regarding which services are primarily delivered in a P3C center (like the PACE center) versus alternative care settings;
- Regulatory flexibility for P3C organizations to engage with individuals with specific disabilities included in the model.

Community Integration

The mission of PACE has always been to provide person-centered medical care and supports that help enable PACE participants to remain in their communities. This mission is reflected in the regulations governing PACE,[10] which would apply to P3C organizations unless waived to enable adaptation of the PACE model of care to better serve the P3C target population (see section 1.f). As in the current PACE model, P3C organizations would be required to provide all Medicare and Medicaid covered items and services without cost sharing and without applying Medicare and Medicaid benefit limitations on the amount, scope, or duration of services, as well as other services determined necessary by the IDT, to improve or maintain the participant's overall health status. After an initial comprehensive assessment performed by the IDT, P3C organizations would be required to work with each participant to establish and implement a written service plan[11] that meets the needs of the participant in all care settings 24 hours a day, every day of the year. P3C organizations would be required to furnish comprehensive health, medical, and support services that integrate acute and long-term care. P3C participants (individuals who enroll in a P3C organization) would be entitled to the same specific rights as in the current PACE program, including the rights to respect, nondiscrimination, and participation in all treatment decisions.

The existing PACE program creates a regulatory foundation, but the P3C model would include a stronger focus on community integration to more appropriately meet the needs and preferences of a younger, mobility-impaired population. Two sources in particular have informed our development of adaptations to the PACE model of care for P3C:

- A January 16, 2014 Medicaid final rule that establishes the requirements and limits applicable to Medicaid Home and Community Based Services (HCBS), including the person-centered planning process and the settings for delivery of those services.[12]

[10] 42 C.F.R. part 460.

[11] In the PACE regulations at 42 CFR § 460.106, the service plan is referred to as the "plan of care." For the P3C model, we prefer to use the term "service plan" as it more accurately captures a plan for the medical and nonmedical services a P3C participant would access.

[12] https://www.gpo.gov/fdsys/pkg/FR-2014-01-16/pdf/2014-00487.pdf

- The Adapted PACE Protocol that was developed by an external work group with representatives from the disability and PACE communities as an operational framework for a comprehensive, capitated and community-based service model, based on the PACE program, and designed for individuals with disabilities and complex medical needs.[13]

Informed by this work, we are considering use of the P3C Request for Applications (RFA) and the P3C Program Agreement (the agreement between the P3C organization, CMS, and the SAA) to establish rigorous standards for community integration for the care/service planning process, the delivery of community supports, and the functioning of the IDT. A pre-implementation readiness review process and our ongoing monitoring of P3C organizations would reinforce these standards. We describe below the potential enhancements to the IDT, assessments and comprehensive service plan, and service delivery approach under consideration for the P3C model.

Interdisciplinary Team

Similar to PACE, we are considering that the P3C model require the use of an IDT responsible for all elements of care/service planning, coordination, and management for each P3C participant.[14] The PACE IDT is comprised of multiple members including individuals responsible for health assessments, service planning, and delivery of medical and behavioral health care and social supports. The intent of having this broad-based team is to coordinate the delivery of medical and behavioral health care and social supports for each PACE participant. P3C organizations would be encouraged to contract with a range of community-based providers to offer participants expanded choice in accessing primary and specialist medical and behavioral health care and community support services in the settings preferred by the participant.

Currently, the PACE regulations require that the IDT include the following members for each participant:

(1) Primary care physician
(2) Registered nurse
(3) Master's-level social worker
(4) Physical therapist
(5) Occupational therapist
(6) Recreational therapist or activity coordinator
(7) Dietitian
(8) PACE center manager
(9) Home care coordinator
(10) Personal care attendant or his or her representative
(11) Driver or his or her representative

[13] See Adapted PACE Protocol at:
http://www.npaonline.org/sites/default/files/PDFs/Adapted%20PACE%20Protocol.pdf
[14] The term "P3C participant" refers to the dual eligible beneficiary who is enrolled in P3C, not to the P3C organization.

We are considering allowing P3C organizations additional flexibility to innovate in the composition of the IDT to respond to the needs of the population of focus, provide for a more streamlined operation of the IDT, and respond to the individual preferences of participants. This could result in some of the IDT members listed above participating in the IDT on an ad hoc basis or taking on more than one role in the IDT if qualified and appropriately licensed to serve in each role. We have previously discussed introducing flexibilities similar to these for the broader PACE population in the PACE notice of proposed rulemaking (NPRM) released earlier this year.

It could also result in additional IDT members not specified above. For example, to address the needs of younger participants, the P3C model could require that behavioral health service providers, employment support/counseling service providers, peer counselors, and housing coordinators on the P3C staff or under contract with the P3C organization be active participants in the IDT, if the participant wants these service providers to be part of the IDT. The key consideration in any evaluation of prospective P3C organizations' proposals to innovate on the IDT model would be that the IDT encompasses the full breadth of service providers used by the participant, including primary care and LTSS, and addresses the needs and preferences of the participant. As under PACE, the IDT would have the authority to authorize (order/prescribe and determine medical necessity) any service within the scope of licensure of the individuals participating on the IDT that is covered under Medicare or Medicaid or determined necessary to improve or maintain the participant's overall health status.

To provide additional flexibility for P3C organizations to innovate in service delivery, we would allow the role of the primary care physician in the IDT to be filled by a primary care provider employed by or contracted with the P3C organization. These could include a contracted primary care physician or specialist selected by the participant, or a qualified and appropriately licensed non-physician practitioner such as physician assistant or nurse practitioner. As above, this flexibility was addressed in the PACE NPRM released earlier this year. We anticipate that certain P3C-eligible beneficiaries would enroll in a P3C organization only if the specialist treating a principle chronic condition, such as multiple sclerosis, had contracted with the P3C organization and was part of the IDT. P3C organizations would be permitted to contract with such specialists who are willing to participate in the IDT process.

Wheelchair and DME competencies

Given the population of focus for the model, we would likely require P3C organizations to demonstrate competence during the joint CMS-state readiness review process (in advance of being approved to accept enrollment) in performing individual assessments for wheelchairs and other durable medical equipment (DME), as well as the modification or repair of such equipment in order to help maintain P3C participants' independence.

Comprehensive Assessments and Person Centered Service Planning[15]

As with care planning in PACE, service planning is the process by which a P3C participant's IDT, under the direction of the participant and/or the participant's caregiver, would develop a single comprehensive service plan to address the participant's medical, functional, psychosocial, and cognitive needs and preferences and achieve measureable outcomes. The service plan would specify both the services that a participant will receive and the setting for receipt of those

[15] Except where waived, PACE regulations for care planning would apply to service planning in P3C.

services. The IDT members who conduct the assessments would collectively discuss with the participant and the other IDT members the participant's self-identified needs, preferences, and goals and design and monitor the participant's individualized service plan.

Initial comprehensive assessments must be conducted promptly after enrollment, which we would define under the P3C model as within 30 days of P3C enrollment. Per PACE regulations that would apply to P3C organizations, periodic reassessments (with attendant modifications of the service plan) would be conducted annually, semiannually, with a change in participant health status, or at the request of the participant or the participant's designated representative. We believe the P3C service plan should identify the most appropriate intervention for each service need, how each intervention would be implemented, and how the intervention would be evaluated to determine progress in reaching the participant's goals and outcomes, and are considering requirements to that effect for this model.

Under the P3C model, we would expect to encourage P3C organizations to contract with community based organizations with expertise in independent service planning that are organizationally independent from the P3C organizations and that provide participants with an advisor to assist participants in self-advocacy in the service planning process.[16] Based on our experience in the Massachusetts One Care demonstration under the Medicare-Medicaid Financial Alignment Initiative, where participating health plans contract with community-based organizations to provide LTSS coordinators to plan enrollees, we believe this expertise could provide participants with a greater ability to lead their service planning process and ensure it addresses their needs and preferences.

Choice of Providers

While PACE typically operates as a staff-model delivery system using employees to provide all care (with the exception of emergency and inpatient care) and PACE participants agree to receive all their services through the PACE organization, PACE organizations are allowed to contract with outside organizations, agencies and individuals for the delivery of PACE services, subject to regulations at 42 CFR §§ 460. 70 and 460.71, including requirements governing training, reporting, and participation in the IDT.

We are considering retaining this basic PACE structure for the P3C model. However, for those newly-enrolling P3C participants who want the flexibility to retain their primary care or behavioral health practitioners who are familiar with their needs and clinical histories, we are considering using the P3C application process and readiness review to encourage P3C organizations to contract with these practitioners with a relationship with the participants, especially specialists used by participants for treatment of the condition or conditions, such as multiple sclerosis, that result in the participant's disability.

Contracts with such practitioners would be required to specify their integration into the IDT and provide compensation commensurate with the additional care coordination work required (although CMS will not dictate payment terms). P3C organizations would be required to promote

[16] For an example of this type of advisor, including potential requirements for expertise and the functions the advisor would fulfill, see the discussion of the Independent Living and Long Term Services and Supports Coordinator in the 3-way contract for the Massachusetts Financial Alignment Initiative, beginning on page 41: https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/MassachusettsContract.pdf

participant self-direction of personal care attendant services that assist P3C participants in performing activities of daily living (e.g. dressing or bathing) and selection of a personal care attendant. P3C organizations would be required to ensure that personal care attendants have appropriate training. Personal care attendants, including those selected by the P3C participant, would participate in the IDT with the consent of the P3C participant.

Reconfiguration of PACE Center

Under the PACE program, the PACE center is a facility which includes a primary care clinic, and areas for therapeutic recreation, restorative therapies, socialization, personal care, and dining, and which serves as the focal point for coordination and provision of most PACE services. The PACE program requires all PACE organizations to operate a PACE center and has detailed physical requirements for these centers, including the availability of a suitable space and equipment to provide primary medical care, therapies, socialization, dining, and personal care attendant services in a manner compliant with state and federal facilities regulations and that protects the participants' privacy and dignity. The PACE center must also have adequate meeting space for IDT meetings. At a minimum, each PACE center must provide primary care services, including physician and nursing services, social services, restorative therapies, including physical and occupational therapy, personal care and supportive services, nutritional counseling, recreational therapy and meals.

The frequency of attendance at the PACE center is established through the care planning process, but PACE participants typically attend several days a week. For many, the PACE center is an opportunity for socialization and a welcome respite from the isolation at home. The PACE center may also be the safest place to bathe, especially for those participants who require a wheelchair but live in housing without an easily accessible shower or bath. Finally, the idea of the PACE center is that all of a beneficiary's needs – including healthcare and social needs – can be addressed in one centralized location.

In many ways, the PACE center is an essential part of the program's success. However, many advocates for people with disabilities have expressed opposition to any PACE-like model where people with disabilities would congregate and socialize separately in a PACE center whose use is exclusively for PACE participants, because that very congregation may impede community integration. To address these concerns, we are considering providing P3C organizations flexibility to innovate in how and where they deliver the full array of P3C services by waiving the requirement that non-medical community support services—specifically, personal care and supportive services, recreational therapy, and meals—be provided at the P3C center. While we would not prohibit delivery of these non-medical community support services at a center location that serves as a delivery site for medical services, we would review any such proposals to ensure the configuration of service delivery maximizes (rather than undermines) community integration for the P3C participants, as described below. We would encourage P3C applicants to explore partnerships with community-based organizations, especially Centers for Independent Living,[17] to provide alternative locations for delivery of non-medical community support services. We

[17] Centers for Independent Living are consumer-controlled, community-based, cross-disability, nonresidential, private nonprofit agencies for the provision of independent living services. See: http://www.acl.gov/Programs/AoD/ILA/Index.aspx#cil

believe that in providing services to both P3C participants and the broader community they serve, such community-based organizations could enhance the integration of P3C participants into that broader community. We are considering requiring that P3C organizations maintain a center, similar to a traditional PACE center, but with some differences to allow for certain services to be provided in alternate locations to promote community integration, as described below.

P3C organizations would need to ensure that P3C participants retain ready access to behavioral and medical care as well as the health and functional monitoring that are integral features of the PACE model of care. Organizations that apply for P3C that intend to arrange for community support services at the P3C center would be required to ensure that the right to privacy for P3C participants seeking medical care is fully respected and the co-location does not compromise delivery of community supports that maximize community integration. It would not be appropriate, for example, for non-medical community supports to be provided in a setting that functions as a waiting room for medical care.

Finally, with the increased focus on independence and community integration in the P3C model, and the use of center locations for delivery of specific medical services and alternative care settings for delivery of specific non-medical services,[18] the role of any venue as a location for socialization—as distinct from recreational therapy—is of diminishing importance. We would expect that any social activities provided by P3C organizations would generally be open to the broader community in order to facilitate community integration.

We are considering a model in which P3C services would generally be provided as follows:

a) Services furnished at P3C centers must include, but are not limited to:
   - Person-centered service planning;
   - Primary care, including physician and nursing services;
   - Restorative therapies, including physical therapy, speech and language therapy and occupational therapy, specialized seating and mobility services;
   - Behavioral health services,
   - Personal care and supportive services as accommodations or adaptations necessary to access the services of the center; and
   - Nutritional counseling.

b) The following services to support community living ("community support services") must be provided in a manner that supports community integration, such as in a home setting or through a community organization. When community support services are provided at a P3C center, the P3C organization – with input from its community advisory committee – should describe in its application ways in which the delivery of services will support community living consistent with the principles of the Medicaid HCBS setting rule at 42 CFR § 441.530.

[18] PACE organizations can currently seek CMS and state approval to deliver some, but not all, PACE services in alternative care settings, typically adult day centers with which they contract, *in addition to a PACE center that provides all required PACE center services.* With the P3C model's enhanced focus on delivery of specific community support services, and the diminished emphasis on social activities in congregate settings, we would not expect P3C organizations to use adult day centers as alternative care settings for delivery of nonmedical services.

- Person-centered service planning;
- Social work services;
- Personal care and supportive services;
- Recreational therapy;
- Meals and other community based services to address food inadequacy;
- Supports and services to find gainful, competitive employment;
- Supports and services that support individuals' ability to secure and maintain community-based housing; and
- Certified peer counseling.

Attendance at the P3C center or alternative care setting for the delivery of nonmedical community support services, including the length of time at any site during a given day and the services or activities accessed at the center, would be directed by the participant, in coordination with the IDT, based on individual preferences and needs as reflected in the service plan. Any P3C center or alternative care setting, whether it provides medical services or community supports, should be focused on delivering specific services in a manner that supports participants' community integration. Similar to current PACE organizations, P3C organizations would be required to set P3C center and alternative care setting open-hours, including non-work and weekend hours, consistent with the needs of participants and the responsibility to make care available 24 hours a day, every day of the year. P3C centers and alternative care settings should be designed to support further integration and facilitate socialization with the broader community beyond other P3C participants. Social activities and the delivery of meals should address the needs and preferences of participants, and be informed by the P3C organization's participant advisory committee. Like other services delivered by a P3C organization, meals and organized social activities should be delivered in a manner that integrates participants in the larger community and scheduled in a way that allows participants to access them without any disruption to their autonomy or control of how they spend their day. As such, transportation accessible to people with disabilities would be required to be available to all P3C center locations and alternative care settings to provide participants with maximum control of their day. To the extent appropriate for the needs and preference of participants, including participants' preference for autonomy, as reflected in participants' service plans, public transportation accessible for individuals with disabilities could serve as a mode of transportation to service locations. Individuals who choose not to receive community support services at the P3C center would need to be able to access services in other settings that promote community integration.

We are considering a requirement that P3C organizations specify how they plan to configure the P3C center and alternative care settings in their applications. CMS would assess P3C applications to determine whether the configuration of the P3C center and the delivery of the full range of P3C services maximizes community integration based on the principles established under the Medicaid HCBS setting rule at 42 CFR § 441.530, specifically looking at whether the community support services:

- 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.

- Are selected by the individual from among setting options including non-disability specific settings. The setting options are identified and documented in the participant-centered service plan and are based on an individual's needs and preferences.
- Ensure an individual's rights of privacy, dignity, and respect, and freedom from coercion and restraint.
- Optimize, but do 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.

P3C organizations would be monitored for responsiveness to the needs and preferences of participants, including through audits, complaints tracking, survey results, and feedback provided by the participant advisory committee. The IDT would be responsible for ensuring that each participant has access to the services he or she needs in the location and time best suited to his or her goals, preferences, and needs.

Governance

Under the current PACE rules, PACE organizations are required to establish a participant advisory committee to provide advice to the governing body on matters of concern to participants. Participants and representatives of participants must make up a majority of the advisory committee. A participant representative must have a seat on the PACE organization's governing body (such as a board of directors). The participant representative acts as a liaison to the governing body from the participant advisory committee and presents issues from the participant advisory committee to the governing body. Under the P3C model, we are considering maintaining this requirement.

In addition, prior to submitting an application, we are considering requiring each prospective P3C organization to establish a community advisory committee with a majority of committee members made up of representatives from local disability rights organizations and potential participants in the P3C organization. The community advisory committee would advise the P3C organization on the development of its application including how it plans to deliver community support services consistent with the standards articulated above. After the P3C organization is approved and enrollment has begun, the P3C organization's participant advisory committee would take the place of the community advisory committee and advise the P3C organizations on how its provision of care is serving to improve participants' integration into the community.

The table below shows the potential differences between the PACE model of care and the P3C model.

Benefits	PACE	P3C	Notes:
Medicare	All A/B/D benefits	No change	
Medicaid	All benefits, including support for community living	No change	
Additional Services	Additional services determined by IDT to improve or maintain participant's health status and integration into the community	No change, although the specific services suitable for the target population will differ.	Benefits may include, as applicable, employment supports; peer counseling; DME assessment, modification and repair; adaptive equipment for the home; self-direction for personal care services
Interdisciplinary Care Team	Composition specified by regulation, waiver requests allowed	Additional flexibility allowed to alter composition	Allows innovation to meet needs of population of focus
Care Planning/Service Planning	By IDT under leadership of participant	By IDT under leadership of participant; encourage use of service/care planning advisor as advocate for the participant	Benefits of a service/care planning advisor include providing participants with a greater ability to lead their service planning process and ensure it addresses their needs and preferences
PACE Center	Locus of primary care by IDT, restorative therapy, nutritional counseling, social work, personal care and recreational therapy and meals; space for socialization; alternative care settings permitted under certain circumstances	Additional flexibility to allow reconfiguration to support principles of Medicaid HCBS setting rule	Allows innovation to meet needs of P3C focus population

Governance	Participant advisory committee; participant participation in governing board	Maintain PACE requirement, and require community advisory committee during pre-application period	Provides vehicle for public input from disability community, including on issues related to community integration

Issues for Comment: We seek comment on the adaptations to the PACE model of care under consideration for the P3C focus population. In particular, we seek input on the following issues:

- Do the potential adaptations to the PACE model of care, especially the flexibility to reconfigure the array of services provided at a P3C center, serve to maximize P3C participants' integration into the community consistent with the principles embodied in the Medicaid HCBS setting rule at 42 CFR § 441.530? If not, what improvements would you recommend?
- Are the elements of the PACE model of care that we are considering retaining for the P3C model appropriate for P3C participants? Should we retain elements of PACE that are not proposed for retention here?
- Do the potential adaptations to the PACE model of care provide sufficient flexibility for P3C organizations to innovate in the delivery of care to meet the needs and preferences of P3C participants? If not, what improvements would you recommend? Additionally, would any of the potential adaptations proposed here undermine the advantages of the PACE model of care delivery? If so, which ones and how?
- Would the potential P3C model described above provide sufficient access by participants to their preferred health care and community support service providers, including specialists? Would additional requirements on P3C organizations be appropriate? How can we best ensure that providers that contract with P3C organizations are integrated into the IDT and service planning process? What mechanism, if any, should we use to encourage P3C participants to contract with community-based providers from which beneficiaries are currently receiving services?
- What are the best ways for CMS and SAAs to assess P3C organizations' ability to perform individual assessments for wheelchairs and other DME as well as the modification or repair of such equipment in order to help maintain P3C participants' independence?
- Does the governance structure under consideration, in particular the requirement for prospective P3C organizations to establish a community advisory committee, provide a reasonable way for people with disabilities to have meaningful input into how the P3C organizations plan to deliver health care and community support services? If not, what improvements or alternatives would you recommend?

1.c Potential Payment Methodology for P3C Organizations

Similar to the current PACE program, P3C would include risk adjusted capitated financing, making P3C organizations responsible for the full continuum of care, including all Medicare Parts A and B and D benefits and all Medicaid benefits. Medicare and Medicaid would each contribute to the total capitation payment, just as Medicare and Medicaid would have each financed a proportion of costs for services to the eligible population had P3C not existed. CMS would develop the Medicare components of the P3C capitation payment. States would develop the Medicaid component, subject to CMS review and approval.

The PIA allows CMS to test new PACE-like models under the authority for the CMS Innovation Center provided in Section 1115A of the Social Security Act. A model tested under Innovation Center authority does not have to be budget neutral initially, but must be expected to achieve budget neutrality or savings to federal spending under the Medicare and Medicaid programs after testing has begun or it would need to be terminated or modified. A similar expectation is required to expand a model through rulemaking.[19] These requirements are important considerations for how we would structure payments under P3C.

The capitation payment would include three distinct components: Medicare Parts A and B, Medicare Part D, and Medicaid. Each is discussed below.

Medicare Parts A and B

We believe that using the current PACE capitation rates and risk model, including the adjustment to payments based on PACE participant frailty, is not the optimal methodology for payment rates that accurately reflect the Medicare Parts A and B costs for the P3C population. The reasons for this are as follows:

- Current PACE capitation rates are based on the Medicare Advantage (MA) county rate methodology in effect prior to enactment of the Affordable Care Act, which paid MA plans more than Medicare fee-for-service (FFS) costs for the broad, MA-eligible population.[20] While research differs as to whether these rates increase Medicare costs compared to Medicare FFS for the population currently enrolled in PACE,[21] on a county-by-county basis they are often above FFS costs in those localities.[22] As a result, the existing PACE rate structure would not be the optimal starting point to develop accurate rates for the P3C population.
- The risk adjustment model used for MA payment beginning in 2017 improves the accuracy of payment for Medicare-Medicaid enrollees living in the community, which are the primary population of focus for the P3C model.[23]
- One of the major differences between the PACE risk adjustment model and MA model is the inclusion of dementia in the former. Dementia is unlikely to be as prevalent a

[19] See Section 1115A(b)(3) and (c) of the Social Security Act.
[20] See MedPAC 2012 at: http://medpac.gov/docs/default-source/reports/jun12_ch03.pdf?sfvrsn=0
[21] See for example Ghosh, 2014, at https://aspe.hhs.gov/sites/default/files/pdf/76976/PACELitRev.pdf and MedPAC 2012 at http://medpac.gov/docs/default-source/reports/jun12_ch03.pdf?sfvrsn=0
[22] See MedPAC 2012 at: http://medpac.gov/docs/default-source/reports/jun12_ch03.pdf?sfvrsn=0
[23] See description of MA risk model at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf

diagnosis in the P3C population under age 55, who are the primary focus of P3C, as it is for PACE participants, nearly half of whom have a dementia diagnosis.[24]

- The frailty model used to adjust payment for PACE is age-specific for older adults, and therefore it is not methodologically tied to the anticipated costs of individuals younger than 55,[25] who are a primary focus of the P3C model.

As a result, for P3C, we are considering two alternative rate setting methodologies.

Option 1: Under the first alternative, Medicare capitation payments would be built from elements of rate-setting currently used in the Medicare Advantage (MA) program.

- The Medicare A/B rate component would be based on the Medicare standardized FFS county rates.[26] The standardized FFS county rates reflect the projected FFS United States Per Capita Cost (USPCC), adjusted to reflect the historic relationship between each county's FFS per capita costs and the USPCC. CMS calculates these geographic adjustments based on historical FFS claims data. The USPCC includes expenditures for Parts A and B services and the associated bad debt payment, disproportionate share hospital (DSH) payments, amounts related to direct and indirect medical education, and federal administrative costs, but excludes hospice services, which are reimbursed through Medicare FFS for MA beneficiaries receiving hospice services. CMS excludes operating indirect medical education and direct graduate medical education payments in establishing standardized FFS county rates, and therefore they would not be factored into the Medicare A/B baseline, consistent with plan payments under MA.
- As in the Medicare-Medicaid Capitated Financial Alignment Model, in some states CMS would also adjust the rates to account for the disproportionate share of bad debt attributable to Medicare-Medicaid enrollees in Medicare FFS (in the absence of the demonstration).
    - See discussion of a potential acuity adjustment below.
- Separate baseline rates would be used for individuals with end-stage renal disease (ESRD). We would use the ESRD state rate for individuals in the dialysis or transplant status phases and the 3.5 star county rate for individuals in the functioning graft status phase, as we have in the Medicare-Medicaid Capitated Financial Alignment Model.
- Amounts would be expressed as per-member per-month standardized rates (i.e. reflecting risk of an average 1.0 population) for each county.
- CMS would risk-adjust payment rates based on the risk profile of each enrolled participant in P3C. CMS would use the prevailing CMS-HCC and CMS-HCC ESRD risk adjustment models (for individuals with ESRD) for P3C, including the new revisions to the CMS-HCC model finalized in the 2017 Medicare Advantage Final Rate Notice. Participant risk scores would be applied to the standardized payment rates at the time of payment.

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[24] See comments from National PACE Association on proposed changes to the risk model at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/RiskAdj2017ProposedChangesComments.pdf

[25] See description of PACE frailty model at: https://www.cms.gov/research-statistics-data-and-systems/research/healthcarefinancingreview/downloads/04-05winterpg1.pdf

[26] See description of MA rate methodology at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Ratebooks-and-Supporting-Data.html

- In the current PACE program, CMS applies a "frailty adjustment" to the Medicare Part C capitation payment to predict costs for the PACE population that the MA risk adjustment model does not predict. This frailty model predicts no additional costs for beneficiaries under age 55 (i.e., these beneficiaries are not, as a population, frail). Because our preliminary analysis shows that the capitated amounts would not equal the FFS paid amounts, we are proposing to apply a different adjustment (an "acuity adjustment") to the standardized FFS county based rate so that the capitation rates under the demonstration reflect the anticipated Medicare A/B FFS spending on beneficiaries eligible for P3C. This analysis also shows considerable county-by-county and year-by-year variation in the amount of adjustment needed to have the final rate reflect A/B FFS spending for beneficiaries eligible for P3C. As a result, the acuity adjustment would reflect a blend of the cost-to-rate differences at the county level and the national level over multiple years of available data to mitigate the effect of the smaller sample size for the P3C-eligible population in individual counties. The proportion of the blend reflecting county-level cost-to-rate differences would be larger in counties with larger presence of P3C-eligible beneficiaries, and therefore more credible cost data. This acuity adjustment, along with underlying rates and A/B FFS costs, is illustrated for counties with a minimum presence of 240 individuals[27] meeting P3C eligibility criteria in data sets that we expect to make available by January 30, 2017 at the following link: https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/index.html

- **Option Two:** As an alternative to the approach above using rates based on the Medicare standardized FFS county rates, we would base rates on contiguous, or non-contiguous, areas larger than a county, such as Core Based Statistical Areas (CBSAs),[28] hospital referral regions,[29] counties with comparable inpatient wage indices, etc., that, because of presence of larger numbers of P3C-eligible beneficiaries, would provide more credibility for developing payment rates based on A/B FFS costs for the eligible population. Such aggregated rates would use an average (weighted by the prevalence of P3C eligible individuals in the counties constituting the larger areas) of the relevant Medicare FFS county rates and otherwise follow the methodologies described above.

Medicare Part D

PACE organizations annually submit a bid for the costs of their projected enrollment of dually eligible enrollees.[30] The Part D payment to PACE organizations comprises several pieces,

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[27] Using 2015 PACE enrollment data, we identified 80 enrollees as the 10th percentile of PACE organizations' enrollment. Assuming potential enrollment of about 1/3 enrollment of eligible beneficiaries, we established 240 eligible beneficiaries per county as the minimum viability threshold for this analysis. The threshold was chosen to present as large a footprint as possible for a P3C model test, including all counties where P3C was potentially viable but not limiting to only counties with credible experience.

[28] See U.S. Census Bureau definition of CBSAs at: https://www.census.gov/population/metro/

[29] See definition of hospital referral region in Dartmouth Atlas of Healthcare at: http://www.dartmouthatlas.org/tools/faq/researchmethods.aspx

[30] PACE organizations also submit a separate bid for their projected Medicare-only enrollment. Since only Medicare-Medicaid enrollees are eligible for P3C, only one bid will need to be submitted by P3C organizations.

including the direct subsidy, reinsurance payments, and risk corridor payments. The Medicare Part D direct subsidy component of the rate is risk adjusted based on the risk profile of each enrolled beneficiary using the CMS-RxHCC risk adjustment model. Payments for eligible participants include a low-income premium subsidy and a low-income cost-sharing subsidy for basic Part D benefits.

PACE Part D payments also include an additional amount to cover nominal Low Income Subsidy (LIS) cost sharing amounts for Medicare-Medicaid enrollees ("2 percent capitation") and an additional premium payment in situations where the PACE organization's basic Part D beneficiary premium is greater than the regional low-income premium subsidy amount. These payments ensure that dually eligible PACE participants are not assessed premiums or copayments for prescription drugs, consistent with the PACE statute, which applies also to the P3C model.

In 2014, the amounts to cover nominal LIS cost sharing amounts averaged $7.52 per member per month (See PACE Cost Sharing Add-on payments in Table A.). The PACE LIS cost sharing amounts are reconciled against actual drug spending and, as a result, the cost sharing payments to PACE organizations end up being equivalent to Low Income Cost Sharing payments other non-PACE Part D sponsors receive to eliminate LIS copays for full Medicare-Medicaid enrollees assessed as requiring a nursing home level of care and either receiving Medicaid home and community-based services or living in a nursing home. We note that the vast majority of P3C participants[31] (as well as most PACE participants) would be eligible for $0 copay if they received Medicaid home and community-based services or were in a Medicaid-paid nursing home stay, and their Part D plans would receive payments to eliminate nominal cost sharing through the Part D low income cost sharing payments.

The premium add-on payments averaged $114.19 per member per month in 2014 (See PACE Premium Add-on payments in Table A). (The increased cost to Medicare of the cost sharing and premium add-on payments is mitigated because these payments count as revenue for risk corridor calculations, serving to further mitigate excessive profits on drug costs for PACE organizations.)

The premium add-on payments that ensure $0 premium basic Part D coverage would create challenges for attaining budget neutrality in P3C payment. Outside of PACE, Medicare-Medicaid enrollees are either reassigned to a $0 premium prescription drug plan, pay the difference between the low income subsidy benchmark and the plan premium out of pocket or, if enrolled in an MA plan, generally have that difference paid by Part C rebate dollars. Only in PACE does Medicare Part D have a liability to ensure $0 premium coverage for Medicare-Medicaid enrollees no matter how much the beneficiary premium in the Part D sponsor's bid exceeds the low income subsidy benchmark.

For the P3C model, we are considering replicating the PACE Part D payment methodology, except that, after three years, we would eliminate the premium add-on payments, and thereby create a pathway to budget neutrality for the P3C model. P3C organizations would submit only

[31] The exception is full dual eligible meeting a nursing home level of care who qualified for Medicaid home and community-based (HCBS) waiver services but were wait listed. See the following for data on waiting lists for HCBS waiver services: http://kff.org/health-reform/state-indicator/waiting-lists-for-hcbs-waivers/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

one bid, since all P3C participants would be dually eligible for Medicare and Medicaid. The Part D payment to P3C organizations would include the direct subsidy, reinsurance payments, low-income cost sharing and premium payments, and risk corridor payments. The Medicare Part D direct subsidy component of the rate would be risk adjusted based on the risk profile of each enrolled beneficiary using the CMS-RxHCC risk adjustment model. Payments for low-income cost-sharing subsidy and for reinsurance would be prospectively established based on P3C Part D bids for dually eligible enrollees and reconciled retrospectively against actual spending under the methodology used for other Part D plans, including Part D plans sponsored by PACE organizations. Risk corridor payments or recoupments would be based on the retrospective reconciliation, with the administrative cost ratio for risk corridors based on the P3C organization bids. Risk corridor bands would follow the prevailing Part D risk corridor methodology.

Under Part D, the low income premium subsidy is the lesser of the Regional Low Income Premium Benchmark in the Part D region or the beneficiary premium for basic Part D coverage in the Part D plan bid. P3C organizations would similarly receive a low income premium subsidy that was the lesser of the Regional Low Income Premium benchmark or the basic beneficiary premium in the P3C organization's Part D bid. However, based on the experience of PACE organizations, we expect that the beneficiary premiums in P3C bids would generally be higher than the Regional Low Income Premium benchmark. For the first three years of an organization's participation in the P3C model, we would fund any difference between P3C Part D beneficiary premiums and the Regional Low Income Premium benchmark with a premium add-on payment, as PACE organizations now receive. These add-on payments would be included as revenue in the calculation of Part D risk corridor adjustments.

After the first three years, we expect that increased enrollment in P3C organizations would substantially reduce, but not eliminate, the additional per-capita costs for administration of the Part D benefit that result in bids by PACE organizations with basic premiums above the regional subsidy amount and require premium add-on payments to fund the resulting revenue shortfall. We also believe that the anticipated phase-out of the premium add-on payments would incentivize P3C organizations to find ways to more efficiently deliver the Part D benefit, including through negotiation of lower drug prices. Any remaining shortfall in the revenue needed for delivering the Part D benefit would have to be funded through savings and efficiencies P3C organizations obtained in the delivery of Medicare Parts A and B services and Medicaid services.

P3C organizations would still receive a 2 percent additional capitation based on the organization bid in order to eliminate nominal low income cost sharing amounts. Low income cost sharing amounts would be reconciled based on Part D drug data submitted, so the final amounts should be equivalent to what would be paid if these individuals were flagged for $0 copay status under Part D because they received HCBS services or were in a Medicaid-covered nursing home stay. We believe the continuation of these cost-reconciled cost sharing subsidies is consistent with budget neutrality, since all P3C participants would have full Medicaid coverage and be assessed as requiring a nursing home level of care, and almost all of these individuals would qualify for $0 copay status if they received HCBS or had a Medicaid nursing home stay absent the

demonstration.[32] The additional LIS payments to bring copays to $0 would not be considered revenue for calculation of risk corridors as they are fully reconciled against drug costs and therefore equivalent to low income cost sharing subsidy payments that would occur absent the model test.

Table A:

	PACE Cost-sharing Add-on Payments Average PMPM	PACE Premium Add-on Payments Average PMPM	PACE Low Income Premium Subsidy Average PMPM
CY 2006	$ 6.16	$ 64.09	$29.71
CY 2007	$ 6.19	$ 65.07	$26.41
CY 2008	$ 6.68	$ 71.54	$25.49
CY 2009	$ 6.90	$ 73.06	$29.29
CY 2010	$ 7.10	$ 80.01	$32.50
CY 2011	$ 7.38	$ 85.60	$34.18
CY 2012	$ 7.72	$ 94.70	$33.77
CY 2013	$ 7.88	$ 122.90	$34.73
CY 2014	$ 7.52	$ 114.19	$ 31.61

Medicaid

Each state and its actuaries would be responsible for developing the P3C Medicaid rate component. As part of CMS review of the Medicaid rate, the state and its actuaries would be required to submit data to CMS to support historical spending levels and utilization and cost trends for Medicaid services.

[32] The exception is full dual eligible individual meeting a nursing home level of care who qualified for Medicaid Home and Community based waiver services but were wait listed. See: http://kff.org/health-reform/state-indicator/waiting-lists-for-hcbs-waivers/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

- Consistent with Section 1934(d)(2) of the Social Security Act, the Medicaid rate must be less than the amount that would otherwise have been paid under the state plan if the participants were not enrolled in the program, as applies in PACE today.
- The P3C Medicaid component may be risk adjusted or distributed into rating categories based on a methodology proposed by each state and agreed to by CMS. This may include the identification of various rate cells/cohorts of the population (e.g., by age or sex, acuity, etc.). We would allow these methodologies to vary from state to state, as they do among PACE programs today.
- CMS would have contracted actuaries to support a coordinated CMS review process that includes the CMS Office of the Actuary.

Potential Risk Sharing Methodology

The variability in the ratio of historic Medicare Parts A and B costs to the rates described above (including risk and acuity adjustment) both on a county-by-county basis and a year-to-year basis creates some uncertainty as to the accuracy of potential P3C capitation rates that could result in either unsustainable losses by P3C organizations or unwarranted gains. The impact of this uncertainty would be heightened during the first three years of a P3C organization's participation in the P3C model, as low initial enrollment in the organization could provide insufficient data to gauge the sufficiency of the rates in relation to the costs of providing services and the high administrative expenses relative to revenue make it more difficult for a P3C organization to absorb losses. In addition, relatively small initial enrollment in a P3C organization (as in typical PACE organizations) and the vulnerability of the population of focus to very high costs for acute medical care or LTSS creates the potential for the costs of a few participants to result in losses for P3C organizations. We are considering addressing both of these risks—the risk of inaccurate rate setting and of very high cost participants—by implementing risk corridor and stop-loss (reinsurance) programs during the first three years of an organization's implementation of the P3C model. We would phase out these risk sharing mechanisms after an initial period of three years in order to provide a clear pathway to achieving increased quality without increasing costs, consistent with the goals of Section 1115A of the Social Security Act to identify models for doing so.

We would look to the experience of the high cost outlier policy implemented for the Rural PACE demonstration in designing the stop-loss program. MedPAC has recommended that Congress establish a similar high-cost outlier protection for new PACE sites after payment rates are made budget neutral,[33] and CMS evaluators noted that an outlier protection fund was critical to successful launch in the Rural PACE demonstrations.[34] Using the parameters of the Rural PACE cost outlier protection program as a starting point,[35] we are considering a P3C stop-loss program that would have the following features:

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[33] See MedPAC 2012 at: http://medpac.gov/docs/default-source/reports/jun12_ch03.pdf?sfvrsn=0

[34]See the Report to Congress evaluating the rural PACE provider grant program at: http://www.npaonline.org/sites/default/files/PDFs/Rural%20PACE%20Report%20to%20Congress.pdf

[35] We note the following potential differences with the Rural PACE Demonstration outlier protection:

- Because the P3C stop-loss program would be jointly funded by the federal and state governments, and not subject to a specific appropriation, we are not currently planning a total limit on federal funding. (The Rural PACE Demonstration program was limited to $10 million.)

- The P3C stop-loss program would reimburse P3C organizations for 80 percent of allowable outlier costs (defined below) paid for a P3C participant that are in excess of $100,000 during any contract year up to the limits described below.
- Allowable outlier costs would be for the provision of Medicare inpatient, related physician and ancillary services, and post-acute services and for Medicaid nursing facility services or personal care attendant services.
- The basis of reimbursement for allowable outlier costs would be the lesser of the Medicare rate plus the cost sharing that would be paid under Medicare FFS by Medicaid for services coverable under Medicare Parts A and B or the rate paid by the P3C organization to contracted providers. For Medicaid services covered under stop-loss, the basis for reimbursement would be the lesser of the Medicaid rate or the rate paid by the P3C organization to contracted providers.
- Funding for stop-loss reimbursement would be paid by the federal government and the state in proportion to their contribution to the capitation payments and based on reporting requirements specified in the P3C program agreement.

We are considering risk corridors that would have the following features:

- Payments and recoupments would be calculated on the basis of total P3C organization spending excluding startup costs (defined as spending prior to start date for enrollment). We are also considering options to limit governmental subsidy of administrative costs.
- Gains or losses would be determined relative to total Medicare Parts A and B capitation and Medicaid capitation payment plus any stop-loss payments.
- Federal and state shares of payments and recoupments would be based on federal and state spending for Medicare Parts A and B capitation and Medicaid capitation payments.[36]
- Risk corridors would be symmetrical, allowing federal and state sharing of P3C organization gains above thresholds and federal and state sharing of P3C organization losses above thresholds. Specific thresholds would be set by agreement between CMS and participating states.
- Federal and state share of gains or losses would be progressively reduced over a three year period starting with the beginning of enrollment for any P3C organization and eliminated

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- We are also considering not imposing per person and per organization thresholds that were used to apportion spending under the $10 million cap.
- The P3Cstop-loss program would cover specified Medicare and Medicaid services and not be limited to Medicare inpatient and related physician and ancillary services as under the Rural PACE Demonstration. We would not want to create an incentive under the P3C stop-loss program to use Medicare covered services instead of Medicaid services. Because we would cover both high cost Medicare and Medicaid services, we are considering doubling the per-person attachment point to $100,000.
- We do not intend to require P3C organizations to exhaust reserve requirements before receiving reimbursement under the P3C stop-loss program because we believe the maintenance of adequate reserves is an important protection for P3C participants. See PACE Rural Demonstration evaluation report for details at: http://www.npaonline.org/sites/default/files/PDFs/Rural%20PACE%20Report%20to%20Congress.pdf

[36] For detailed description of a methodology similar to the one we are considering, see Section 4.3.1 of the Rhode Island Financial Alignment Initiative Contract at https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/RhodeIslandContract.pdf

after the third year of the organization's implementation of the P3C model. Final risk sharing percentages would be agreed with participating states. The following percentages are provided as illustrative examples.

- In the first year:
  - Greater than 5 percent gain/loss, the P3C organizations would bear 10 percent of the risk/reward; the state and CMS would share in the other 90 percent;
  - Between 1.5 percent and 5 percent gain/loss, the P3C organization would bear 50 percent of the risk/reward, the state and CMS would share in the other 50 percent;
  - Between 0 percent and 1.5 percent gain/loss, the P3C organization would bear 100 percent of the risk/reward.
- In the second year, the respective P3C organization and CMS/state shares in each risk/reward corridor would remain consistent but the corridors would widen to: 0 percent to 2 percent; between 2 percent and 6 percent; and greater than 6 percent.
- In the third year, the respective P3C organization and CMS/state shares in each risk/reward corridor would remain consistent but the corridors would widen to: 0 percent to 2.5 percent; between 2.5 percent and 7 percent; and greater than 7 percent.

Quality-Based Payments

We are also considering the potential of adjusting P3C payments based on performance on specific quality measures reported by P3C organizations once the organizations have achieved financial stability based on the rates described above and the organizations have sufficient enrollment to serve as the basis for valid and reliable quality measures.

Coding Intensity

In the Medicare Advantage program and elsewhere, we have seen evidence of increased coding of beneficiary conditions when payment is linked to those conditions. We expect that we may face similar issues in this model. Therefore, we expect to monitor coding of beneficiary conditions, and we are considering making across-the-board cuts to P3C participant Medicare reimbursement if we determine that P3C participants are increasing coding intensity for their beneficiaries, whether appropriately or inappropriately, as compared to similar beneficiaries that remain in the traditional Medicare program. We are considering use of comparisons to similar counties with P3C participants and other comparison methodologies to evaluate whether increases in coding intensity are occurring, and we intend to release annually an analysis of this issue.

Summary

The table below summarizes the potential differences between PACE and P3C with respect to payments.

Payment Parameter	PACE	P3C	Notes:
Medicare A/B financing	Capitated, based on PACE base rate based on pre-ACA MA county benchmarks	Capitated, but with closer tie to FFS costs under one of two options: Standardized FFS county rates; blended FFS county, at CBSA or other aggregate level	Adaptation needed to ensure the viability of P3C organizations and meet the requirements of Section 1115A that spending does not increase
Medicare A/B risk adjustment	Risk model is based on a prior MA model, plus dementia and other codes, plus a frailty adjustment	Uses prevailing MA risk adjustment model instead of current PACE risk adjustment model and an acuity adjustment in place of PACE frailty adjustment	
Part D financing	Direct Subsidy, Reinsurance, Low Income Premium and Cost Sharing Subsidy; Additional capitation to ensure no premium for LIS eligible and $0 copays	Similar methodology but with phase-out of premium add-on payments. P3C organizations would submit only one bid for dually eligible participants	Phase out of premium add-on payments provides pathway to budget neutrality
Part D risk adjustment	Rx-HCC model (as in MA)	No change	
Medicaid	Rate set by states subject to CMS review and upper payment limits	No change	Ensure rate setting meets the requirements of Section 1115A regarding impact on federal spending
Risk Sharing for Medicare A/B and Medicaid	None	Provide, for first 3 years of participation in the P3C model: Stop-loss payments for P3C participants with very high costs for specified Medicare and Medicaid services; Risk Corridors for Medicare A/B and Medicaid capitation	Phase out of risk sharing arrangements provides pathway to budget neutrality

Issues for Comment: We seek comment on the payment methodology described above. In particular:

- From states, would you be willing to participate in the stop-loss (reinsurance) and/or risk corridor mechanisms under consideration? Would the potential CMS Medicaid rate review process work for P3C?
- From prospective P3C applicants, we welcome any information about the payment amounts necessary to have a viable, sustainable model. To what extent are risk-sharing mechanisms necessary to start-up? Are other factors more important? Is reinsurance coverage already available on the commercial market? Would it be feasible after an initial start-up period to fund stop-loss protections from reductions in capitation rates? Would other funding mechanisms be preferable to back-end risk protections for managing P3C start-up?
- What additional information may be necessary to assess the financial viability of the model prior to implementation?
- Are the potential risk adjustment and base payment mechanisms reasonable for the P3C population of focus? Which of the two Medicare A/B rate setting options presented above would yield the most accurate, stable and viable rates for P3C organizations? Do you agree that the PACE Medicare A/B rates and risk model are inappropriate for a P3C model test under Section 1115A of the Social Security Act? Are there other options we should consider?
- What would be the most reasonable ways in a risk corridor to limit potential government subsidy of high administrative costs under the risk corridor proposal?
- What is the best way for the government to assure that the overall payment methodology results in budget-neutral payments for P3C participants? Specifically, if we add a risk corridors program or outlier policy, for either a limited initial period or as a permanent feature of payment, would we need to reduce P3C capitation payments accordingly?
- We are concerned that, if we provide higher payment rates or additional protections only early in the model, participants may leave the model after the phase-out of a risk corridors program. What mechanisms could we use to alleviate this concern?
- What is an appropriate time period after which Part D PACE premium add-on payments should be phased out and the payment methodology targeted to achieve budget neutrality? Are there alternative means to attain budget neutrality in PACE Part D payments that would be more financially viable for P3C organizations?
- What are appropriate quality metrics on which we could adjust payment? How can we ensure such payment adjustments are budget neutral?
- What would the best strategy be for us to limit or mitigate excess payments to P3C participants due to increases in coding intensity? What monitoring strategies would be most effective? And how should we modify payments to P3C participants if we find evidence of increased coding intensity, as compared to similar beneficiaries who remain under traditional Medicare?

1.d Proposed Quality Outcomes for Evaluation of P3C Model

We believe the P3C model would result in improved health outcomes, greater integration into the community, and an enhanced experience of care and quality of life for participants receiving services from P3C organizations. The test for this hypothesis would be based on assessment of select encounter data, survey results, and quality measures that P3C organizations would be required to report. The quality outcomes used for ongoing assessment and monitoring of P3C organizations' performance and the independent evaluation would supplement the existing PACE quality reporting requirements[37] and would include:

- Community Integration
  - Measures for days of institutional vs. community living (claims/encounter data)
- Health Outcomes
  - Hospitalization, preventable hospitalization and readmissions measures (claims/encounter data)
  - Measures for completion of assessment (P3C organization reporting)
  - Measures for service plan development (P3C organization reporting)
  - Immunization and screening measures
  - Participant-reported health outcomes
    - Survey results
    - Assessment tool results for:
      - Functional status
      - Depression
  - Other relevant health outcomes reported by P3C organizations, including:
    - Pressure ulcer measures
    - Appropriate medication utilization, such as medication adherence, generic utilization
- Experience of Care and Quality of Life, including integration into the community
  - Survey results (e.g. CAHPS, surveys used for LTSS assessment)

Issues for Comment: We seek comment on the above quality outcomes under consideration for evaluation of the P3C model. In particular, we ask commenters to address the following issues:

- Is the reporting required for the quality outcomes described above likely to be feasible for P3C organizations?
- What existing surveys and quality measures would be appropriate to obtain the quality information described above?
- What other quality outcomes not described above should be included in the evaluation of a P3C model?

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[37] PACE organizations currently report on their quality assessment and improvement activities, immunizations, enrollments, disenrollments, grievances and appeals, readmissions and emergency care use, unusual incidents and deaths under Level 1 reporting. Level 2 reporting includes reporting on pressure ulcers, falls, traumatic injuries, deaths and infectious disease outbreaks. PACE organizations survey their members using the Health Outcomes Survey- Modified (HOS-M). PACE quality reporting requirements are described in Chapter 10 of the PACE Manual, available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pace111c10.pdf

1.e Potential Operational Structure for P3C

We are considering using the existing CMS and state PACE operational infrastructure to implement and conduct oversight of the P3C model, with modifications appropriate to the different needs for this model's implementation. We believe this would maximize efficiency, and provide a structure familiar to the states that will be implementing the model with us. In general, the existing PACE regulations at 42 C.F.R. part 460 and the PACE Manual,[38] unless waived, would function as operational guidance for P3C organizations, including for enrollment and disenrollment, appeals and grievances, and organization governance. To the extent feasible, communication with P3C organizations would occur through the Health Plan Management System (HPMS), which is presently used for PACE.

Application Process

To allow time for more organizations to prepare for and apply to the model without delaying those applicants that would be prepared first, we are considering accepting applications on a rolling basis. We would encourage both existing PACE organizations and other capable entities to apply to become P3C organizations. CMS would accept P3C applications using a modified version of the PACE application and the PACE Part D application. We would also evaluate the applications for criteria specific to the model, including:

- Availability at P3C centers and through alternative care settings or delivery mechanisms, of all health related and social support services to maximize community integration;
- Availability at P3C centers, or through alternative care settings or delivery mechanisms, of disability competent care suitable for the population of focus, including fitting and repair of DME;
- Support from the community advisory committee in the development of the application;
- Availability of participant-directed personal attendant and community support services.

The application would have to include an assurance from the SAA that it is willing to enter into a P3C Program Agreement with CMS and the organization (see "Readiness Review" below). The application would also have to provide assurances from the SAA that it would coordinate its oversight and rate setting activities with CMS and provide Medicaid data necessary for the evaluation.

CMS intends to provide an opportunity for interested stakeholders and organizations to comment on a draft of the P3C application before posting the final version.

Readiness Review

After submission of an application to participate in the P3C model and prior to approval, CMS and the SAA would complete a readiness review assessing whether the organization is ready to become operational and accept enrollment. Principal criteria for the readiness review would include availability of existing staff and contractors to provide the full range of required services,

[38]See PACE Manual at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019036.html

safety of the P3C center and alternative care settings, and ability to meet other P3C requirements through established policies and procedures.

Monitoring

During the P3C model test, on a quarterly basis, we expect that the P3C organization would submit monthly operational and statistical data to CMS and the SAA regarding basic information such as number of referrals, number of individuals enrolled, number of individuals disenrolled, number of grievances, etc. This monitoring plan would incorporate the elements of the more intensive monitoring of new PACE organizations during each PACE organization's three-year trial period, including comprehensive assessments of the P3C organization's fiscal soundness, capacity to provide all required services, and compliance with applicable PACE regulations and terms of the P3C Program Agreement. It also would incorporate existing PACE Level 1 reporting requirements (e.g. immunizations, readmissions, emergency (unscheduled) care, deaths) and Level 2 reporting requirements (e.g., falls, traumatic injuries, infectious diseases outbreaks, pressure ulcers).[39] We also expect to require reporting that would track the use of self-directed care, the provision of training in disability-competent care, and the hours of personal attendant care provided.

Enrollment Processes

We expect that the P3C model would utilize current PACE voluntary enrollment processes adjusted to target enrollment to the specific population eligible under the P3C model. To be eligible for PACE, individuals must: be 55 years of age or older; be determined by the SAA to need the level of care (LOC) required under the state Medicaid plan for coverage of nursing facility services; reside in the PACE organization's service area; be able to live safely in a community setting at the time of enrollment; and meet any additional program-specific eligibility conditions imposed under its respective PACE Program Agreement. Under P3C, the intake process would be modified to allow enrollment of individuals meeting the P3C eligibility requirements.

Under the P3C model, the responsibility for the nursing home LOC assessment would remain with the state assessment utilizing the LOC tool documented in the Medicaid state plan. P3C organization staff still would need to assess potential participants at intake to ensure they can be served appropriately in a community setting, under criteria agreed upon by CMS and the SAA and incorporated in the P3C Program Agreement. The service area would be defined in the P3C organization's application and the P3C Program Agreement. The additional elements of the intake process, as well as a signed enrollment agreement would be updated to reflect new model-specific requirements, but the process will remain the same as PACE.

Similar to the PACE intake process, we expect that P3C staff would conduct an assessment of the individual's care support network as well as the individual's health condition to determine whether or not his or her health and safety would be jeopardized by living in a community setting based on criteria established in the P3C Program Agreement. We are interested in hearing

[39] See PACE Manual Chapter 10 for more detail: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pace111c10.pdf

from states on whether this assessment could be made by the SAA, in conjunction with state level of care assessments.

In the intake process, the P3C organization would make an initial assessment to determine that the individual has the conditions required for enrollment in P3C, including mobility-impairment related diagnoses. The qualifying diagnoses would be confirmed at the individual's initial assessment by the IDT.

Summary

The table below summarizes potential differences between PACE and P3C.

Operations and Oversight and Quality Reporting	**PACE**	**P3C**	**Notes:**
Application Process	PACE Application and PACE Part D application	PACE Application with addition of model-specific narrative for P3C center, IDT composition; PACE Part D application	Use separate process for submission, application includes narrative of policies and procedures etc. to verify compliance
Contract	3-Way Agreement with state, CMS and PACE organization	Existing 3-way agreement with modifications to reflect terms specific to the model	Take into account model-specific terms and conditions and program waivers with state-specific contract requirements as addenda (e.g. for licenses)
Readiness Review	Conducted by state for solvency, center requirements prior to application	Joint CMS-state review (with support from CMS contractor) post-application for fiscal soundness, contracted providers, readiness to provide disability competent care, use of P3C center to maximize community integration	
Audits and Monitoring	Periodic audits by CMS regional offices	Audits adapted to include P3C requirements; more frequent monitoring of P3C sites, especially at inception of demonstration	Leverage CMS regional office PACE expertise and infrastructure and supplement with contractor support
Reporting	Reporting on enrollment, critical incidents	No change	
Enrollment	Voluntary Enrollment and Disenrollment; Eligibility based on age, NHLOC and safety assessment	Voluntary Enrollment and Disenrollment; Eligibility based on P3C eligibility criteria	

Quality Measurement	Includes reporting on immunizations, critical incidents, Health Outcomes Survey	More robust measure sets based on claims, assessment tools and surveys	Meets requirements for independent evaluation

Issues for Comment: We seek comment on the operational structure discussed above, including the issues identified below:

- Do the P3C application and oversight processes under consideration strike the right balance between federal and state roles? If not, what improvements would you recommend?
- Are the criteria for review and approval of applications from potential P3C organizations appropriate? What improvements would you recommend?
- Are the readiness review and monitoring plans described above, including the data elements, appropriate for the P3C model?
- Would it be feasible for SAAs to confirm qualifying diagnoses as part of the level of care assessments?
- Is it feasible and beneficial to standardize the assessment of potential participants' ability to live safely in the community across all participating states?
- Would additional requirements to ensure the fiscal soundness of P3C organizations be appropriate? Would it be feasible to increase the reserve requirements to better ensure P3C participants are better protected in the event a P3C organization is ending participation in the model?
- What monitoring of P3C organizations to protect against waste, fraud, and abuse would be appropriate and effective?
- Are there additional considerations for striking the right balance between accountability for the P3C organization and promoting self-direction, community integration, and dignity for P3C participants?

1.f Potential Program Waivers under Section 1115A of PACE Statutory Provisions

Under the authority at Section 1115A of the Social Security Act, codified at 42 U.S.C. § 1315a, the Innovation Center is authorized to "…test payment and service delivery models …to determine the effect of applying such models under [Medicare and Medicaid]." As modified by the PIA, Section 1115A(d)(1) of the Social Security Act includes the authority to waive such requirements of sections 1934 and 1894 of the Social Security Act (the statutory authorities for PACE under the Medicaid and Medicare programs, respectively) as may be necessary for purposes of carrying out Section 1115A with respect to testing models. As specified by the PIA, the Secretary may not waive the requirements of section 1934(b)(1)(A) of the Social Security Act (requiring PACE organizations to offer all items and services covered under Medicare and Medicaid without limitation), or section 1934(c)(5) of the Social Security Act (requiring PACE organizations to comply with certain requirements regarding enrollment and disenrollment).

We are considering waiving the PACE provisions described below as necessary for the model test. No waivers of any kind are being issued in this document, which merely describes the program waivers contemplated at this time for the model; waivers, if any, would be set forth in separately issued documentation.

Except as waived, Sections 1115A, 1934, and 1894 of the Social Security Act and 42 C.F.R. part 460 would provide the authority and statutory and regulatory framework for P3C during the model testing period, as well as for periods preceding and following the model testing period as applicable to allow for related implementation and closeout activities. Any conforming exceptions to the existing PACE Manual will be noted and reflected in an appendix to the P3C Program Agreement.

- For the purposes of defining the required composition of the IDT and the comprehensive assessment criteria, CMS interprets 42 CFR §§ 460.102 (IDT) and 460.104 (Participant assessment) to fall under §§1934(b)(1)(C) and 1894(b)(1)(C) of the Social Security Act, which require PACE organizations to provide services to PACE participants through a comprehensive, multidisciplinary health and social services delivery system. Similarly, for the purpose of defining the activities required to take place at the P3C center, CMS interprets 42 CFR §§ 460.6 (Definitions), 460.64 (Personnel qualifications for staff with direct participant contact), 460.72(a)(2) (Physical environment of PACE center), 460.98(c) (Minimum services at each PACE center), 460.98(d) (PACE center operation), 460.98(e) (PACE center attendance) to fall under either or both §§ 1934(b)(1)(B) and 1934(b)(1)(C) and §§1894(b)(1)(B) and 1894(b)(1)(C) of the Social Security Act. Pursuant to the foregoing authority, CMS would waive the following statutory and regulatory requirements:
  - Sections 1934(j) and 1894(j) of the Social Security Act to the extent they are reflected in 42 CFR § 460.150(d) (Eligibility to enroll in a PACE program), only insofar as such provisions are inconsistent with limiting enrollment in P3C to individuals who are entitled to benefits under Medicare Part A and enrolled under Medicare Part B, and eligible to receive full Medicaid benefits.
  - Sections 1934(a)(5)(A) and 1894(a)(5)(A) of the Social Security Act to the extent they are reflected in 42 CFR §§ 460.4(b) (PACE purpose to serve frail, older adults) and 460.150(b)(1) (Age requirement for PACE eligibility), only insofar as such provisions are inconsistent with limiting enrollment in P3C to individuals who are 21 years of age or older.
  - Sections 1934(b)(1)(C) and 1894(b)(1)(C) of the Social Security Act to the extent they are reflected in 42 CFR §§ 460.102 (IDT), and 460.104 (Participant assessment) only insofar as such provisions are inconsistent with the IDT policy as outlined in the P3C RFA and P3C Program Agreement.
  - Sections 1934(b)(1)(B) and 1934(b)(1)(C) and Sections 1894(b)(1)(B) and 1894(b)(1)(C) of the Social Security Act to the extent they are reflected in 42 CFR §§ 460.6 (Definitions), 460.64 (Personnel qualifications for staff with direct participant contact), 460.72 (Physical environment), 460.98 (Service delivery) only insofar as such provisions are inconsistent with the definition of personnel qualifications and PACE center requirements as outlined in the P3C RFA and P3C Program Agreement.
  - Sections 1934(d)(1), 1934(d)(2), 1894(d)(1), 1894(d)(2), and 1894(d)(3) of the Social Security Act, and implementing regulations at 42 CFR §§ 460.180 (Medicare

Payment to PACE organizations), 460.182 (Medicaid Payment to PACE organizations), 460.184 (Post eligibility treatment of income), and 460.186 (PACE premiums) only insofar as such provisions are inconsistent with the methodology for determining payments under P3C as specified in the P3C RFA and P3C Program Agreement.

- The provisions regarding deemed approval of marketing materials in Sections 1934(f)(3) and 1894(f)(3) of the Social Security Act and implementing regulations at 42 CFR § 460.82 (Marketing), with respect to marketing and participant communications materials in categories of materials that CMS and the state have agreed will be jointly and prospectively reviewed, such that the materials are not deemed to be approved until both CMS and the state have agreed to approval.

Issues for Comment: We seek comment on the potential program waivers described above for the P3C model. In particular, we ask for comments addressing the following issues:

- Do the potential waivers described above provide sufficient flexibility for P3C organizations to implement the P3C model of care as proposed? What additional waivers would be needed to implement the P3C model?
- Are there additional waivers needed for P3C organizations to innovate in the delivery of care?
- How can we best use the application process and P3C Program Agreement to set limits on specific waivers?

1.g Model Evaluation Design

Under Section 1115A of the Act, we must evaluate the quality of care furnished under a model and changes in Medicare and/or Medicaid spending that result from implementation of the model. This potential P3C model poses several evaluation challenges. We note that, without a rigorous evaluation, we will not be able to derive any learnings from this model to inform future models and policy decisions. In other words, in order for the PACE organization and federal and state resource investments necessary to conduct this model to be worthwhile, we must design the model with a robust evaluation plan in mind.

First, the potential model, as outlined here, would have a relatively small sample size, especially on a per organization basis, making it difficult to detect small changes in either cost or quality. Given the current size and scale of PACE and the demands of a potential P3C model, there may also be a small number of P3C organizations participating in this model, which would further compound our small sample size problem.

Second, the potential model, as outlined here, may have a limited geographic scope. PACE is not available in all states, and it is unclear whether a sufficient number of P3C organizations in rural and urban areas would participate to allow for a thorough evaluation of the model's differential impacts across varying geographic regions.

Third, since state Medicaid programs may have flexibility to vary model design parameters and do have flexibility to vary certain PACE organization compliance regulations and statutes, state-by-state variations could affect our ability to detect or generalize based on a small change in

either cost or quality. Additionally, depending on the concentration of P3C participants within a state, it may be difficult to find an adequate comparison group.

Prior to the beginning of the application submission process, CMS may provide information pertaining to an evaluation strategy for a P3C model. Several strategies exist that could be applied individually or in various combinations to help us overcome these evaluation hurdles. We list several examples below:

- **Randomization of Beneficiaries**: CMS could employ a random selection of beneficiaries in each area with an approved P3C applicant into a model intervention (treatment) group eligible to enroll in the P3C organization and a non-intervention (control) group ineligible for P3C enrollment. Randomized approaches to evaluation design are often used to measure the impact of an intervention by minimizing the potential for selection bias between treatment and control group beneficiaries. This approach faces potential challenges based on the number of P3C sites selected and the numbers of beneficiaries eligible for enrollment with each P3C organization and across all selected P3C organizations.
- **Randomization of Geography**: CMS could employ a design that includes assignment of geographic areas into predefined strata and then the random assignment of the geographic areas in these strata into treatment and control areas. We could then limit applications to only certain regions that fit pre-identified geographic treatment group areas. While not meant to be an exhaustive list, potential strata could include Medicaid program characteristics --including regional expenditure differences on LTSS; spending based on supply of LTSS providers or differences in regional or state-based approaches to the existing PACE program.
- **Post-Intervention Control Group Selection**: We could select a control, or comparison, group following our selection of participating, P3C organizations. This model design would best guarantee participation, but create the largest difficulties in separating out cost and quality changes, even of substantial size, from other confounding factors.

Issues for Comment: We seek comment on the potential evaluation approaches we lay out above and how each approach balances the need to conduct a rigorous evaluation to determine model learnings with the desire to encourage participation.

- Are there any additional threats to the evaluation of this potential model that we should consider? What are these threats?
- Are there specific operational or ethical challenges to any of the evaluation approaches noted above that we should consider?
- Are there any evaluation strategies that could mitigate the threats listed above that we have not considered here? If so, what are they?
- What evaluation strategy best balances the need for a rigorous evaluation with the desire to achieve sufficient model participation? For the chosen evaluation strategy, how can we best ensure efficient use of federal, state, and model participant resources through robust evaluation able to detect real changes in cost and quality?

General Comment: We seek stakeholder input on additional issues raised by our description of the potential P3C model. We are particularly interested in hearing from people with disabilities regarding the description of the model and how it could be improved to better meet the full range of medical and social needs and preferences of the disability community. We are also interested in feedback from states and potential P3C organizations regarding their interest in participation in the model and any changes to the model that would facilitate their ability to participate.

Part II: Additional Potential Populations for a Model Test

We are interested in testing adaptations of the PACE model of care for individuals with complex medical needs whose current interactions with the health care delivery system too often result in suboptimal care, poor health outcomes, and high costs. In particular, we believe there is potential for adaptations of the PACE model of care to integrate a range of services currently provided in a fragmented manner. This could be accomplished through the integration of disparate payment streams which can result in improved outcomes and lower costs. Integrated care through an adaptation of the PACE model of care also has the potential to provide seamless care as individuals transition across federal health care programs with changes in eligibility. In particular we seek input on how to adapt the PACE model of care to the following populations currently ineligible for PACE, or for whom PACE is not an available option:

- Older individuals with Medicare (with and without Medicaid) who do not require nursing home level of care, but require additional non-medical supports to remain in the community;
- Individuals with Medicare (including individuals under age 55, with and without Medicaid) who have End Stage Renal Disease and who are receiving dialysis treatment;
- Individuals with Medicare and/or Medicaid (including individuals under age 55) who have severe and persistent mental illness;
- Individuals with Medicare and/or Medicaid who have intellectual or developmental disabilities (including individuals under age 55)
- Individuals with Medicare (with and without Medicaid) who receive support for community living through U.S. Department of Veterans Affairs programs (including individuals under age 55);
- Individuals with Medicare and/or Medicaid, including individuals in the categories described above, living in rural communities.

We are seeking comment on the above populations as well as any additional populations that you believe would benefit from application of the PACE model of care.

We are also seeking comment on appropriate criteria for identifying the populations of focus, including, as applicable:

- Clinical criteria (including specific identifiers, such as ICD-10 codes)
- Nursing Home Level of Care
- Alternative functional status or diagnostic criteria instead of Nursing Home Level of Care
- Assessment mechanism for identifying eligible individuals

- Age Criteria

Improved Health Outcomes and Quality Measurement:

We are seeking comment on the potential health (including psychosocial) benefits of the application of a PACE-like model for the populations recommended above, including benefits to family and caregivers.

We are seeking comment on the outcomes that should be measured to assess the impact of a PACE-like model on the recommended populations' health, functional status, satisfaction, and quality of life. Include specific quality measures (e.g. HEDIS, CAHPS, HOS) where applicable.

We are seeking comment on modifications, including additions, to the PACE model of care that would be needed to fit the needs of the populations of focus, including:

- Composition of IDT (including additions)
- Requirements for a PACE Center
- Assessments and care planning processes
- Use of self-direction for long term services and supports
- Use of technology to support care coordination and community integration
- Enrollment mechanisms
- Integration of additional services (e.g. employment support, housing assistance)
- Use of contracted services for provision of care
- Other

In describing recommended modifications, please specify the statutory and regulatory provisions that would need to be waived.

Payment and Costs:

We are seeking comment on a capitated payment methodology for provision of Medicare and Medicaid services that would provide a sustainable basis for a PACE-like model focusing on these populations, while meeting statutory requirements under Section 1115A of the Social Security Act to maintain budget neutrality or achieve savings.

Please address applicability and potential modifications to:

- Existing PACE rate methodology for Medicare and Medicaid
- Medicare Advantage (MA) rates
- Risk adjustment models (including MA risk model, and rate cells for long term services and supports)
- State rates established for managed long term services and supports
- Risk sharing (e.g. risk corridors, reinsurance)
- Medicare Part D payment

We are also seeking comment on the specific changes to utilization of services that would be expected as a result of the application of a PACE-like model for the populations of focus.

Support Infrastructure:

We are seeking comment on the applicability, and potential modifications to the demonstration of the following:

- PACE application
- Readiness review process
- Quality reporting

General Comment:

We are seeking additional comments, including questions that would need to be addressed, in testing the application of the PACE model of care to new populations.

SPECIAL NOTE TO RESPONDENTS: Whenever possible, respondents are asked to draw their responses from objective, empirical, and actionable evidence and to cite this evidence within their responses.

THIS IS A REQUEST FOR INFORMATION (RFI) ONLY. This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal, applications, proposal abstracts, or quotations. This RFI does not commit the Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. Not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. Please note that CMS will not respond to questions about the policy issues raised in this RFI. CMS may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become Government property and will not be returned. CMS may publically post the comments received, or a summary thereof.