The Center for Elder Care & Advanced Illness is focusing on the Program of All-Inclusive Care for the Elderly (PACE) as a highly promising, existing model that can be adapted to meet the needs of large numbers of Medicare beneficiaries (as well as dually eligible beneficiaries) who require a mix of medical care and LTSS. These beneficiaries need reliable, well-coordinated, geriatrically competent, longitudinal services that are organized to be delivered in the community. They must be affordable both to participating seniors and to U.S. taxpayers.

This analysis, Current Barriers & Possible Solutions: PACE Regulatory Flexibility Provisions That Would Help Medicare-Only Enrollees, explains the specifics of key regulatory flexibilities in four areas that are central to successful PACE expansion and scaling to a broad Medicare population. The document includes links to relevant current regulatory and statutory policy:

1. **Flexible Premium Rates for LTSS Based on Assessed Need**
   This centers on a way to give PACE programs enhanced flexibility to develop premiums for Medicare-only beneficiaries in the form of comprehensive tiered packages.

2. **Two-Way Contracts to Allow Development of PACE Plans Serving Interested Medicare Enrollees**
   This highlights the need to clarify guidance to explicitly allow for two-way contracts between PACE providers and Medicare in order to remove barriers for Medicare-only beneficiaries who wish to enroll in PACE the opportunity to do so in states across the country.

3. **Enhancing Part D Affordability**
   This addresses a regulatory path forward for giving Medicare-only beneficiaries the ability to exercise the option of choosing a more affordable Part D plan outside of PACE.

4. **Expanding to Medically Complex “At Risk” Medicare Beneficiaries**
   This examines the need to develop and test a model for medically complex Medicare beneficiaries who are “at risk” of spending down to Medicaid but who do not yet meet their state’s nursing home level of care eligibility requirement (which varies significantly across the country).
Proposal 1 - Flexible Premium Rates for Services and Care Based on Assessed Need
Allow PACE organizations more flexibility in offering premiums charged to Medicare-only beneficiaries.

The PACE authorizing statute calls for “capitated, integrated funding that allows the provider to pool payments received from public and private programs and individuals.” The statute is silent on the amount of private payment that Medicare-only Nursing Home Level Of Care (NH LOC) enrollees should be charged for Long Term Services and Supports (LTSS), but that is referenced in regulation.

**Statute:** Sec. 1934. [42 U.S.C. 1396u-4]  
(d) Payments to Pace Providers on a Capitated Basis.—  
(1) In general.—In the case of a PACE provider with a PACE program agreement under this section, except as provided in this subsection or by regulations, the State shall make prospective monthly payments of a capitation amount for each PACE program eligible individual enrolled under the agreement under this section.  
(2) Capitation amount.—The capitation amount to be applied under this subsection for a provider for a contract year shall be an amount specified in the PACE program agreement for the year. Such amount shall be an amount, specified under the PACE agreement, which is less than the amount that would otherwise have been made under the State plan if the individuals were not so enrolled and shall be adjusted to take into account the comparative frailty of PACE enrollees and such other factors as the Secretary determines to be appropriate. The payment under this section shall be in addition to any payment made under section 1894 for individuals who are enrolled in a PACE program under such section.

**Statute:** Sec. 1934. [42 U.S.C. 1396u-4]  
(f) Regulations.—  
(1) In general.—The Secretary shall issue interim final or final regulations to carry out this section and section 1894.  
(2) Use of PACE protocol.—  
(A) In general.—In issuing such regulations, the Secretary shall, to the extent consistent with the provisions of this section, incorporate the requirements applied to PACE demonstration waiver programs under the PACE protocol.  
(B) Flexibility.—In order to provide for reasonable flexibility in adapting the PACE service delivery model to the needs of particular organizations (such as those in rural areas or those that may determine it appropriate to use non-staff physicians according to State licensing law requirements) under this section and section 1894, the Secretary (in close consultation with State administering agencies) may modify or waive provisions of the PACE protocol so long as any such modification or waiver is not inconsistent with and would not impair the essential elements, objectives, and requirements of this section, but may not modify or waive any of the following provisions:  
(i) The focus on frail elderly qualifying individuals who require the level of care provided in a nursing facility.  
(ii) The delivery of comprehensive, integrated acute and long-term care services.  
(iii) The interdisciplinary team approach to care management and service delivery.  
(iv) Capitated, integrated financing that allows the provider to pool payments received from public and private programs and individuals.  
(v) The assumption by the provider of full financial risk.

**Regulation:** CMS HHS Title 42 §460.186 PACE premiums.
The amount that a PACE organization can charge a participant as a monthly premium depends on the participant’s eligibility under Medicare and Medicaid, as follows:  
(a) Medicare Parts A and B. For a participant who is entitled to Medicare Part A, enrolled under Medicare Part B, but not eligible for Medicaid, the premium equals the Medicaid capitation amount.  
(b) Medicare Part A only. For a participant who is entitled to Medicare Part A, not enrolled under Medicare Part B, and not eligible for Medicaid, the premium equals the Medicaid capitation amount plus the Medicare Part B capitation rate.  
(c) Medicare Part B only. For a participant who is enrolled only under Medicare Part B and not eligible for Medicaid, the premium equals the Medicaid capitation amount plus the Medicare Part A capitation rate.  
(d) Medicaid, with or without Medicare. A PACE organization may not charge a premium to a participant who is eligible for both Medicare and Medicaid, or who is only eligible for Medicaid.
CMS' explanation on medicare.gov about PACE states that Medicare-only enrollees will be charged "a monthly premium to cover the long-term care portion of the PACE benefit." Accordingly, the forthcoming PACE final rule could be modified to provide PACE plans with the flexibility, in consultation with CMS, actuaries, and, where appropriate, the state Medicaid program, to develop and offer Medicare-only beneficiaries at NH LOC (and who are not financially eligible for Medicaid) an additional option to purchase specific service and care packages that correspond to their level of assessed comprehensive need. A tiered monthly premium, with fully transparent and disclosed costs, would be charged to the beneficiary for those services. The options would include paying either for one of these tiered premium packages or a premium equal to a state's PACE Medicaid average capitation rate, which may be below or above the average Medicaid capitation rate, and the PACE program would continue to be at full risk for all benefits.

If an enrollee's service or care needs change, additional services would be provided by the PACE plan immediately at no additional cost to the beneficiary, prior to and contemporaneous with reassessment and revision of the care plan. Following re-assessment, if a determination that substantial additional services are needed on an ongoing basis, the PACE plan would transition the enrollee to a tier that includes those additional services at a higher monthly cost. With regard to timing, the additional needed services would be supplied immediately after the reassessment and revision of the care plan; the new premium would start with the first of the month that is at least one month into the future (and all lower tier monthly fees would incorporate an amount to insure the PACE program against this likelihood). The premium tier structuring would not limit or reduce the PACE organization's responsibility to provide all-inclusive benefits to enrollees in accordance with their needs. To make this possible, PACE plans should be allowed to develop different services and care packages at tiered rates, in consultation with CMS and actuaries.

Because PACE has long been viewed as a program serving primarily dually eligible people, current regulations offer Medicare-only beneficiaries only a single option for using their own private funds to buy into PACE. Regulations require that the premium be the full Medicaid capitation rate, which is an average rate (the national average is about $2300 per month). This amount may be too high for many Medicare beneficiaries who may have more limited LTSS support needs and finances or more access to volunteer help, and who might otherwise wish to enroll, both to acquire reliable services in a comprehensive care model, and to conserve personal financial resources. Medicare-only beneficiaries and their families often greatly misunderstand the financing of long-term services, and the high single rate requires more rapid learning than many consumers can accomplish quickly, and commonly results in "sticker shock." A more flexible approach may prove to be more readily understandable by Medicare-only beneficiaries and their families, which is important since this choice must be made at the time of enrollment.

Proposal 2 - Two-Way Contracts To Allow Development of PACE Plans Serving All Interested Medicare Enrollees.

Allow PACE organizations to contract with Medicare.

PACE program agreements for Medicare-only enrollees are not discussed explicitly in either the authorizing statute or in regulations. However, Medicare-only beneficiaries are enrolled in some PACE programs, and CMS' website at medicare.gov acknowledges this.

| Statute: Sec. 1894, [42 U.S.C. 1395eee] (a) Receipt of Benefits Through Enrollment in Pace Program; Definitions for Pace Program Related Terms.  
(4) PACE PROGRAM AGREEMENT DEFINED.—For purposes of this section, the term 'PACE program agreement' means, with respect to a PACE provider, an agreement, consistent with this section, section 1934 (if applicable), and regulations promulgated to carry out such sections, between the PACE provider and the Secretary, [emphasis added] or an agreement between the PACE provider and a State administering agency for the operation of a PACE program by the provider under such sections. | Regulation: CMS HHS Title 42 CFR §460.30 Program agreement requirement.  
(a) A PACE organization must have an agreement with CMS and the State administering agency for the operation of a PACE program by the PACE organization under Medicare and Medicaid.  
(b) The agreement must be signed by an authorized official of CMS, the PACE organization and the State administering agency.  
(c) CMS may only sign program agreements with PACE organizations that are located in States with approved State plan amendments electing PACE as an optional benefit under their Medicaid State plan.  

Possible Solution

Regulatory clarification allowing PACE program agreements for Medicare-only enrollees to be entered into between the PACE provider and the Secretary for Medicare-only enrollees.

Rationale

Today, Medicare beneficiaries wishing to enroll in PACE cannot do so in 19 states that do not have PACE as a Medicaid option. If federal regulatory interpretation were made more flexible to permit PACE plans to get underway via two-way agreements, thus allowing Medicare beneficiaries who can pay for their LTSS services out of pocket to enroll, the likely result would be to reduce the risk of spending down to poverty via more prudent care planning and community supports. Additional flexibility permitting expanded plan choice for Medicare-only beneficiaries across the country is therefore prudent.
Proposal 3 - Part D Enhanced Affordability

Allow Medicare-only beneficiaries who enroll in PACE to select an affordable Part D plan from the marketplace available to other Medicare participants, rather than requiring them to enroll in the Part D Plan of the PACE organization.

Current regulatory interpretation of the 1997 authorizing PACE statute predates the Medicare Modernization Act of 2003 and subsequent regulations covering Part D. One anomalous result is that Medicare-only NH LOC beneficiaries enrolled in PACE are the sole cohort that is required to pay full price for their drug coverage in the form of extremely high Part D premiums. The premium incorporates the cost of what would be out-of-pocket payments in conventional Part D plans, which are predicted to be high for this ill and disabled population. These Medicare-only PACE NH LOC enrollees are also not deemed eligible for federal subsidy payments for catastrophic costs and for manufacturer discounts for brand-name drugs during the donut hole (because they are not directly paying deductibles and co-payments and thus, technically, never reach the donut hole). They are not allowed to select among Part D plans available in their area with regard to coverage and affordability (because that would seem to require that they pay for a Medicare-covered service outside of PACE). In addition, PACE programs currently enroll relatively small numbers of seniors, making their administrative costs high.

From CMS Guidance PACE Manual: Ch. 13 - 40.5 Part D PACE program participants who have Medicare only will receive their qualified prescription drug coverage through Medicare Part D and will be responsible for a monthly premium. PACE program participants who have Medicare and also qualify for the State Medicaid program will be deemed eligible for the Part D Limited-Income Subsidy which will cover their monthly premium for Medicare Part D. As part of the PACE Program Agreement, the PACE organization agrees to calculate and collect beneficiary Part D premiums, to the extent applicable, in accordance with 42 CFR §§ 423.286 and 423.293.

Under these rules, medication costs for dually eligible PACE participants are a pass-through for the PACE program, which has neither financial risks nor benefits from providing the beneficiaries’ drugs. But Medicare-only PACE participants are confronted with a Part D fee that has none of the benefits of discounts and federal catastrophic support that is routine for all other Medicare beneficiaries. Explaining this to a NH LOC Medicare beneficiary and his or her family is extremely difficult, especially when the PACE Part D premium is higher by a factor of 7 to 10 times what they would otherwise pay.

Statute: Sec. 1894. [42 U.S.C. 1395eee]
(b) SCOPE OF BENEFITS; BENEFICIARY SAFEGUARDS.—
(1) IN GENERAL.—Under a PACE program agreement, a PACE provider shall—
(A) provide to PACE program eligible individuals enrolled with the provider, regardless of source of payment and directly or under contracts with other entities, at a minimum—
(i) all items and services covered under this title (for individuals enrolled under this section) and all items and services covered under title XIX, but without any limitation or condition as to amount, duration, or scope and without application of deductibles, copayments, coinsurance, or other cost-sharing that would otherwise apply under this title or such title, respectively; and
(ii) all additional items and services specified in regulations, based upon those required under the PACE protocol;

(f) Application To PACE.—
(1) In general.—Subject to paragraphs (2) and (3) and rules established by the Secretary, in the case of a PACE program under section 1894 that elects to provide qualified prescription drug coverage to a part D eligible individual who is enrolled under such program, the provisions of this part (and related provisions of part C) shall apply to the provision of such coverage to such enrollee in a manner that is similar to the manner in which such provisions apply to the provision of such coverage under an MA-PD local plan [emphasis added] described in section 1851(a)(2)(A)(ii) and a PACE program that so provides such coverage may be deemed to be an MA-PD local plan.
(2) Limitation on enrollment.—In applying paragraph (1), the organization may not enroll part D eligible individuals who are not enrolled under the PACE program involved.
(3) Bids not included in determining standardized bid amount
The bid of an organization offering prescription drug coverage under this subsection is not be taken into account in computing any average benchmark bid amount and low-income benchmark premium amount under this part.
Possible Solution

Consider modifying Part D regulations and guidance to exempt Medicare-only PACE enrollees – as VA PACE enrollees are now – from the requirement to enroll in only the PACE Part D plan. PACE Part D premium payments are currently waived for VA-eligible PACE enrollees, as noted below, and a similar arrangement could be made for Medicare-only eligible PACE enrollees. In that case, for Medicare-only beneficiaries, CMS could alter regulations to allow the beneficiary to pay to the PACE program an actuarial estimate of the cost of applicable copayments, deductibles and other out-of-pocket costs. Then, Medicare-only beneficiaries at NH LOC who enroll in PACE could choose either the PACE Medicare Part D plan or another Part D plan available in their area. If they chose the marketplace plan, they would pay the PACE program the relevant premium and the supplemental amount estimated to cover copayments, deductibles, and other out-of-pocket costs, and the PACE program would pay the invoices on their behalf. This would meet the statutory requirements for the PACE program.

From CMS Medicare Prescription Drug Benefit Manual: Ch. 14 - Appendix F Waiver for VA-eligible PACE Enrollees:

Existing PACE regulations at 42 CFR §423.30(c) require that the PACE provide all Medicare-covered services, including Part D prescription drug coverage. In addition, Part D regulations at 42 CFR §460.92 require Medicare-only enrollees to pay the PACE program a fee that is actuarially equivalent to the projected monthly cost of their prescription drug benefits from their PACE organization. As a result, PACE enrollees who are also eligible for the VA benefit must receive prescription drug coverage through their PACE organization and Medicare-only PACE veterans must pay a significant Medicare Part D premium to the PACE organization to obtain the drug coverage. The arrangements between the VA and PACE organizations, by facilitating coordination of prescription drug benefits between the VA and Medicare, permitted CMS to waive the requirements in §423.30(c) thus permitting PACE veterans to receive prescription drug coverage through the VA and avoid paying the Part D premium [emphasis added]. PACE organizations with a service agreement with a VAMC received notification from CMS of the waiver of §423.30(c), which was issued under the authority of §423.458(d) which permits waivers of requirements as necessary to improve coordination between Part D and PACE. The notice also stated that CMS was granting the PACE organizations a conditional, organization-wide waiver of §460.92 of the PACE regulation under the authority of section 903 of the Benefits Improvement and Protection Act of 2000, permitting PACE enrollees eligible for VA drug coverage to choose to receive drug coverage through the VA.

Taking all of this into consideration, modified regulations could allow Medicare-only enrollees to pay the PACE program a fee that is actuarially equivalent to the projected monthly cost of their prescription drug benefits. The plan would assume the risks and administrative complexities of paying a Part D marketplace plan. For Medicare-only enrollees, costs accruing from choosing a marketplace Part D plan would be substantially lower than if forced to purchase PACE Part D coverage, in part due to eligibility for discounts for brand-name drugs during the donut hole period, federal payment in the catastrophic coverage zone, and the reduced cost of being in a large insurance pool. The two components of the monthly fee owed to the PACE plan would be understandable – one is the cost of the PACE Part D plan, and the other is the predicted cost of the deductible, co-pay, donut hole, catastrophic coverage, and medications not covered by Part D.

Dually eligible PACE enrollees do not pay premiums, deductibles, copayments and other costs and do not have a choice of Part D plans. A typical PACE Part D premium costs more than $700 per month, which is many times more expensive than Part D premiums in marketplace plans. Medicare-only PACE enrollees, who are responsible for paying their Part D premiums through the PACE program (as explained above), should have the freedom to choose among available Part D plans, which will necessarily be affected by various factors including the composition of the formulary, premium amounts, and other factors.
### Proposal 4 - Expanding to Medically Complex “At Risk” Medicare Beneficiaries

Under the PACE authorizing statute, Medicare beneficiaries who do not meet their state’s NH LOC eligibility requirements cannot enroll in PACE.

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<thead>
<tr>
<th>Statute: Sec. 1894, [42 U.S.C. 1395eee][1894(a)(5)]</th>
<th>Regulation: CMS HHS Title 42 CFR §460.150</th>
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<td>(c) Eligibility Determinations.— (2) CONDITION.— An individual is not a PACE program eligible individual (with respect to payment under this section) unless the individual's health status has been determined by the Secretary or the State administering agency, in accordance with regulations, to be comparable to the health status of individuals who have participated in the PACE demonstration waiver programs. Such determination shall be based upon information on health status and related indicators (such as medical diagnoses and measures of activities of daily living, instrumental activities of daily living, and cognitive impairment) that are part of a uniform minimum data set collected by PACE providers on potential PACE program eligible individuals.</td>
<td>Eligibility to enroll in a PACE program. (2) Be determined by the State administering agency to need the level of care required under the State Medicaid plan for coverage of nursing facility services, which indicates that the individual's health status is comparable to the health status of individuals who have participated in the PACE demonstration waiver programs. This cannot be waived under BIPA 903 waivers, because current regulations further state:</td>
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<td>(f) Regulations.— (1) In general.— The Secretary shall issue interim final or final regulations to carry out this section and section 1934. (B) Flexibility.— In order to provide for reasonable flexibility in adapting the PACE service delivery model to the needs of particular organizations (such as those in rural areas or those that may determine it appropriate to use nonstaff physicians according to State licensing law requirements) under this section and section 1934, the Secretary (in close consultation with State administering agencies) may modify or waive provisions of the PACE protocol so long as any such modification or waiver is not inconsistent with and would not impair the essential elements, objectives, and requirements of this section, but may not modify or waive any of the following provisions: (i) The focus on frail elderly qualifying individuals who require the level of care provided in a nursing facility.</td>
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### Possible Solution

Consultations can begin with interested stakeholders in the PACE community and among researchers and advocates to help guide development of an RFP for expansion of PACE to the non-NH LOC, medically complex, at-risk Medicare-only population under the authority of the PACE Innovation Act of 2015 (S. 1362, then Public Law No: 114-85). The Explanation of Provision section of the Senate Finance Committee’s Report provides clarification of requirements that cannot be waived by the PACE Innovation Act. That Report clarifies that the Secretary cannot waive the requirement to offer “all items and services covered” under Medicare and Medicaid without limitation to PACE program enrollees.

State criteria for “nursing home level of care” vary substantially. Within demonstration authority under the PACE Innovation Act, the Secretary has the ability to examine the merits of selecting a uniform standard (e.g., 2 or more ADLs or requiring constant supervision) to enable similarly situated individuals with progressive disabilities and advanced illnesses to participate. There are a substantial number of Medicare beneficiaries today (and tens of millions more in the future) who have serious conditions -- such as Alzheimer’s-related dementias, Parkinson’s syndrome, and frailty -- who would benefit from PACE comprehensive assessment, care planning and individually tailored, ongoing services available through the program, e.g., day center support, provision of geriatric medical care, physical therapy and caregiver support. A growing body of evidence shows that comprehensive planning and reliable provision of selected services reduces caregiver stress and lowers utilization of high-cost services. Therefore, using PACE more broadly quite likely slows spend-down to Medicaid. To build out the case for PACE expansion and scaling, we recommend that CMMI and MMCO cooperate in testing the merits of expanding PACE enrollment to a population that has serious and worsening chronic disease and associated disabilities requiring both medical care and LTSS.

### Rationale

Medicare beneficiaries who have some LTSS needs and wish to enroll in PACE, which is an attractive community-anchored, longitudinal program with comprehensive services, should have the option to do so, thereby conserving their personal financial resources and gaining access to a source of high-quality, longitudinal care that includes both medical services and community-based LTSS. Taxpayers and states will benefit if policymakers take sensible steps to ensure that Medicaid does not become the program of first resort for the rapidly rising population of older adults living long lives, 70% of whom will need LTSS.