PACE & PART D:

A TALE OF TWO STATUTES IN NEED OF A SOLUTION FOR MEDICARE BENEFICIARIES

ALTARUM

SOLUTIONS TO ADVANCE HEALTH

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Acknowledgments

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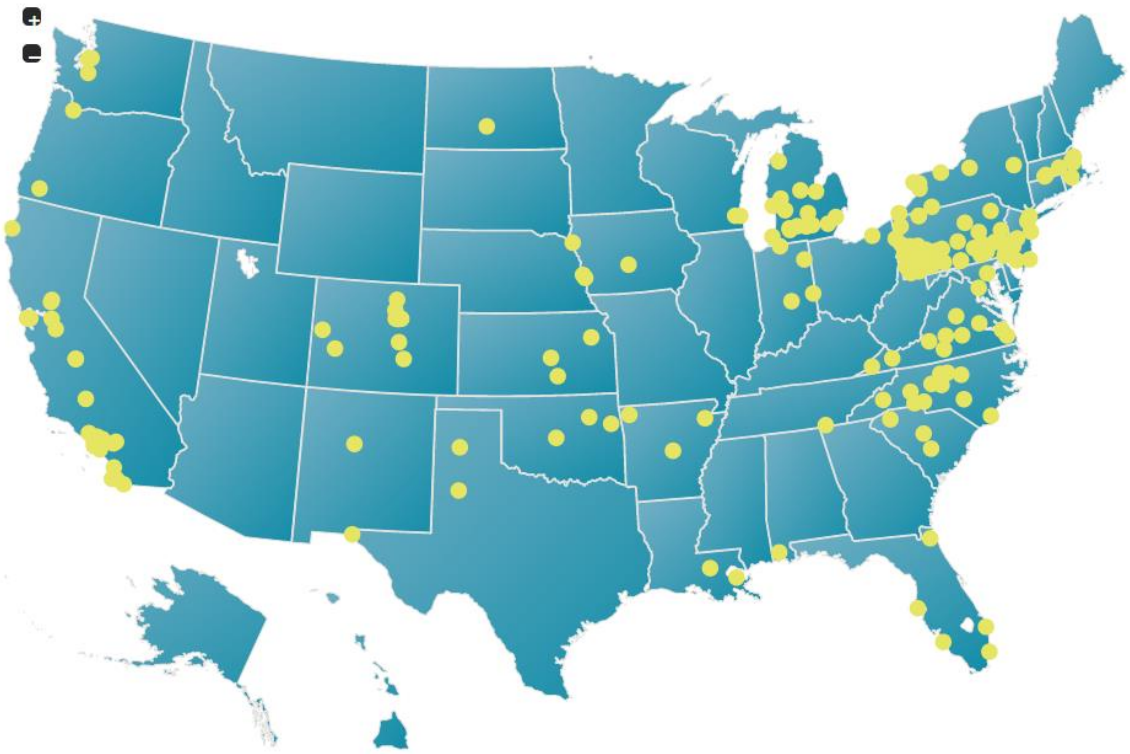
What Did This Foundation-Funded Project Set Out to Achieve?

In February 2019, the Massachusetts-based Rx Foundation provided an award to Altarum for a two-year project aiming to make a strong case for resolving a longstanding misalignment between the PACE program, enacted into federal law in 1997, and the Medicare Part D benefit, enacted as part of the Medicare Modernization Act of 2003.

PACE organizations provide services in 30 states to about 57,000 eligible people. One reason for the slow growth of PACE is the high cost of drugs for Medicare-only PACE participants.

Exhibit 1. Locations of PACE organizations in the United States
Source:* *National PACE Association



As a well-established program -- a high-quality, flexible model of integrated care that has significant potential to slow middle-class spend-down to Medicaid – it seems likely that if the PACE Part D dilemma can be resolved, more Medicare beneficiaries will opt to buy into PACE. In part, this is because PACE is a highly regarded program, and a growing number of Medicare beneficiaries are or will be seeking reliable sources of long term supports and services (LTSS) as they age and develop functional limitations. The federal government is in an ideal position to expand high-quality Medicare integrated care by making PACE more available to the middle-class “pre-duals” population.

Over a three-year period (with a "gap" year in 2020) Altarum thoroughly explored the policy and political landscape around what we call the PACE and Part D dilemma – the fact that non-dual Medicare beneficiaries buying into PACE are required to purchase a very costly PACE Part D plan -- with no other choices offered -- that costs them an eye-popping $1000 per month. In doing this work, we have collaborated closely with a leading actuarial firm, Milliman, Inc. -- specifically Frank Kopenski, principal and consulting actuary. Milliman's work was independent and not funded by Altarum, the National PACE Association (NPA) or Rx Foundation grant proceeds. In addition, we have worked alongside staff at NPA. We have presented feasible policy solutions (briefly summarized on p. 5 and subsequently discussed in detail). We have focused on the legislative pathway in discussions with dozens of advocacy organizations that are members of the Leadership Council on Aging Organizations (LCAO) and the Disability and Aging Collaborative (DAC) -- the two major coalitions based in Washington, D.C. focusing on older adults with disabilities.

Our interim grant report submitted in March 2020 detailed the specific work we undertook in the first year to advance solutions for Medicare beneficiaries wishing to enroll in PACE to be able to "buy in" (by paying for their own LTSS out-of-pocket), which is equal to the amount of their state's Medicaid PACE capitation rate, while simultaneously purchasing a standalone Part D Plan (PDP) that provides affordable Part D coverage. We also sought and received permission to expand our work to include an extensive look at how PACE could potentially expand to meet the needs of a broader population of Medicare beneficiaries who could benefit from the highly coordinated medical and LTSS services that the PACE program provides.

In separately funded work, we conducted a detailed economic and program design analysis for a California PACE organization on how they can market and deliver packages of LTSS services as a straightforward extension of their existing PACE program, thereby expanding their footprint in that state's growing population of middle-class Medicare beneficiaries who need LTSS but are not yet eligible for Medicaid.

As we expanded and deepened our PACE expansion analyses, our initial evidence, gathered in focus groups with families for a project with Huron Valley PACE in Ypsilanti, Michigan -- was strengthened. The tiny number of non-dual PACE participants enrolled in the program (fewer than 200) is evidence that Medicare beneficiaries understand it is not sensible to pay more than 20 times the price for prescription drug coverage. It follows that the severe Part D price penalty that Medicare beneficiaries must pay to enroll in PACE today is also a major barrier to the program's ability to reach the pre-dual population.

> *"To Medicare beneficiaries, being told you have to pay $1100 a month for your prescription drug coverage when every other drug plan in the market costs less than $35 sounds like a scam, or a mistake. Huron Valley PACE has developed a federal waiver to solve this problem, and there are legislative solutions available too. There is a real desire to decrease prescription drug costs, and we can start here." – Sonja Love Felton, Huron Valley PACE*

Altarum also analyzed the structural problems underlying the PACE Part D dilemma: Due to conflicts in current statutory and regulatory interpretation of PACE and Part D, PACE Part D plans are designed to provide no cost-sharing assistance and are structured as a 100% benefit. For Medicare beneficiaries who are also PACE participants, the result is an exorbitant Part D premium that is on average 22-fold higher than any other PDP option available in the competitive marketplace. Specifically, the monthly PACE Part D premium -- more than $900 per month, or 38% of the average Medicare beneficiary's annual income -- also raises questions of equity and price discrimination for current Medicare-only PACE participants who find themselves caught in the PACE Part D cost vise.

It is possible to solve these issues by activating any of the options described below, each of which would provide Medicare-only PACE participants with access to exactly the same coverage, rebates and limits on out-of-pocket costs that all other Medicare beneficiaries enjoy today. Part D possible solutions include:

- **Proposed Solution #1: Waiver Approach.** Allow individual PACE organizations to apply for a BIPA 903 waiver. Once approved, PACE organizations would offer Medicare-only PACE participants at the time of enrollment a choice of paying for their Part D coverage through the PACE Part D plan or obtaining it through a PDP. One example of this approach was developed by Altarum and Huron Valley PACE (see pgs. 9-10).
- **Proposed Solution #2: Systemwide Waiver.** Offer all Medicare-only PACE beneficiaries a choice of a PACE Part D plan or a local Part D PDP. A precedent for this approach is the 2011 BIPA 903 waiver granted in 2011 for Medicare-eligible veterans (see pgs. 10-13 for further details).
- **Proposed Solution #3: Legislative Approach.** Allow PACE participants a choice of prescription drug coverage at time of enrollment. Coverage is through the PACE organization's Part D plan or through a local Part D PDP. This possible pathway is embodied in the PACE Part D Choice Act (see p. 13).

In effect, this final grant work product both spotlights and puts into context the administrative waiver solution originally designed by Altarum, and submitted by Huron Valley PACE of Ypsilanti, Michigan, in 2018 under the PACE waiver authority that was established in the Benefits Improvement and Protection Act of 2000 (BIPA), section 903, and under Part D waiver authority. The financial impact analysis provides a guide to how the Congressional Budget Office (CBO) could view the potential cost of the PACE Part D Choice Act, originally introduced in 2019, to the federal government, if enacted into federal law. The bill, led by Reps. Earl Blumenauer, Jackie Walorski, Debbie Dingell and Chris Smith, would allow Medicare beneficiaries to choose either a PACE Part D plan or a PDP.

"PACE provides coordinated health care services to transportation, companionship and support and many other things for seniors in one place and a community that cares. As our nation's population continues to age, we have to look at increasing access to PACE for Medicare-only participants. Right now, these PACE participants currently make up only 1% of the enrollees. More should have the right to a place in the community where they feel they belong, can get help, make and enjoy friends and find empathy and compassion." – Congresswoman Debbie Dingell (D-MI)

Altarum, in conjunction with Milliman, created an important new analysis for Congressional and executive branch staff on the projected financial impact of providing Medicare-only PACE participants with the option of selecting an affordable Part D PDP in late 2021. The dollar amounts featured in the independent Milliman financial impact analysis are well below the threshold CBO typically includes in their reviews of economic impact (which also normally only cover federal government costs). The additional one-year, one-time cost to the Centers for Medicare and Medicaid Services (CMS) in 2022 would be $106,000; for all Rx manufacturers, $621,000, and for all Part D PDPs, $324,000. In contrast to these very small, non-recurring costs, for non-dual Medicare beneficiaries, the savings in 2022 alone are $1.7 mil, according to Milliman's Power Point presentation.

Altarum and Milliman presented these findings in briefings designed for senior staff working for three key congressional Committees – Senate Finance, House Ways & Means, and the Senate Special Committee on Aging. Similarly, we sent the financial impact analysis to senior HHS officials -- including the CMS Chief Operating Officer, the HHS Assistant Secretary for Legislation, and the director of the Medicare-Medicaid Coordination Office -- highlighting relevant findings, and offered briefings tailored to their interests. The presentation slides can be found in Appendix B.

Principal findings from the presentations are quoted and displayed in the main body of this report. The economic analysis derives from 2022 Part D bid data and highlights the substantial cost relief that Medicare-only PACE participants would realize if either an administrative or legislative solution were adopted that allowed them the option of choosing an affordable PDP. The presentation also displays the one-time, one-year costs to other key stakeholders – Part D PDPs, pharmaceutical manufacturers and the federal government, which would be so minor as to be negligible.

BACKGROUND: THE RISING NEED FOR INTEGRATED CARE

In 2018, Medicare beneficiaries with four or more chronic conditions, made up 40% of the population, an increase of 4% from 2010.[1] The Affordable Care Act provided states with options to provide additional home and community-based services (HCBS) options through Medicaid and strengthened the Medicare program in a range of ways, including the development of promising models of care through the Center for Medicare and Medicaid Innovation.

Still, in too many states, middle-class Medicare beneficiaries continue to lack good options for highly integrated care. This is particularly important for those who need LTSS to receive support for functional and/or cognitive limitations or assistance with social determinants of health (SDH), e.g., meal preparation and household help, to enable safe and supported aging in place.

[1] Lochner, K.A., Cox, C.S.. (2010) Prevalence of Multiple Chronic Conditions Among Medicare Beneficiaries. *Prev Chronic Disease. 2013;10.* Accessed at https://www.medscape.com/viewarticle/807545.

Participants must be certified by their state as needing a nursing home level of care and assessed by the PACE organization as being able to live safely in the community (at the time of enrollment) with support. PACE services are only available in the 30 states that elected to authorize the Medicaid state option and in many states are not available state-wide.

PACE plans are at full financial risk and held responsible for providing all Medicare and Medicaid-covered services. PACE programs deliver some of these services directly in the PACE center, which serves as a medical center and a place for social activities and LTSS support, through its 11-member interdisciplinary team. PACE programs also commonly contract with other organizations, e.g., a hospital or a rehabilitation center and with specialists for other services. PACE frequently chooses to cover services that are determined necessary by the interdisciplinary team to improve or maintain an individual's overall health status. For complex older adults, outcomes described in the literature (a sample of which are summarized in the next section) generally show that PACE participants experience fewer hospitalizations and less institutional care than other similarly situated beneficiaries. Once enrolled, few PACE participants choose to leave, and the program typically enjoys high levels of satisfaction.

> As a mature integrated care model, PACE is community-based, comprehensive in its benefit scope, coordinated across medical and LTSS care, and capitated across Medicare and Medicaid. PACE programs serve individuals who are 55 and older and live within a designated geographic service area that is assigned to a PACE organization (which can be expanded).

Although PACE has excellent potential to slow spend-down to Medicaid among a middle-class "pre-dual" Medicare population (compared to those paying for a nursing home stay), the PACE Part D barrier has long stymied the ability of the program to attract this group of beneficiaries. As of December 2021, there were 142 PACE plans in 30 states serving nearly 60,000 adults. Only a tiny fraction – less than 1% of PACE enrollees – were Medicare-only.

PACE: AN ESTABLISHED, HIGHLY COORDINATED CARE MODEL

A sampling of studies from the literature (see Appendix A) demonstrates positive overall findings for PACE in achieving low hospitalizations, with one study finding that "PACE enrollees experienced lower rates of hospitalization, readmission, and [elevated blood pressure] than similar populations," and another concluding that short-term hospital utilization among PACE participants is "low in contrast with that for other older and disabled populations."

Broader research comparing PACE with other HCBS programs indicates that PACE enjoys "improved health management outcomes, increased preventive care, and reduced hospital use," increased short-term nursing home stays, and overall "more appropriate use of services… [as well as] better self-reported health status, including the same levels of functioning, and fewer depressive symptoms.[2]" (The same study found that PACE participants had more

[2] The Effect of the Program of All-Inclusive Care for the Elderly (PACE) on Quality, Jody Beauchamp, 2008.

behavioral incidents.) Other studies affirm that PACE programs make sparing use of institutional care, especially for individuals living with dementia, with "PACE services significantly reduc[ing] unexpected hospital admissions of persons with dementia (PwD), [and] facilitate[ing] the maintenance of physical independence and improved cognitive performance and mood status."

Finally, most PACE programs consistently report high levels of participant and caregiver satisfaction: "Satisfaction with PACE services tends to be high, as evidenced by low disenrollment rates and self-report by participants and caregivers. Participants in PACE services tend to fare better on a number of outcomes, including decreased mortality, better control of pain, and higher rates of completion of advance directives.[3]"

CHALLENGES EXPLORED AND ADDRESSED

While PACE has frequently been praised as a "gold standard" model of care for high-risk older adults with disabilities, it has also often been dismissed as a "boutique" program that is unlikely to scale. In work that Altarum has done during the last 5 years across several projects, we set out to prove otherwise.

In a Michigan Health Endowment Fund supported project that began in 2017 with Huron Valley PACE in Ypsilanti, MI, we analyzed several possible scaling strategies to expand PACE to a growing Medicare population that needs and wants comprehensive services. Specifically, Altarum explored three possible pathways: 1) enroll Medicare beneficiaries who need LTSS services, are nursing home eligible and can afford to pay the state's PACE Medicaid capitation rate; 2) devise access pathways for Medicare beneficiaries who are slightly above the state's income eligibility limit for Medicaid and are eligible for nursing home level of care (LOC) but not able to pay the full PACE Medicaid capitation rate; and 3) serve

"St. Paul's Senior Services started the first PACE program in San Diego in 2008. Since that time, we have helped thousands of low-income individuals at risk of nursing home placement receive integrated and holistic care. Our Board of Directors challenged us to look at implementing the PACE model for middle/higher income individuals with complex medical and social needs. We now add our support for allowing flexibility for middle-class individuals to purchase a more affordable Part D plan so that they too can receive the gold standard of care and reduce overall health costs in our nation." – Ellen Schmeding, Chief Operating Officer, St. Paul's Senior Services

America's Health Rankings analysis of U.S. HHS, Centers for Medicare & Medicaid Services, Research, Statistics, Data and Systems, United Health Foundation, AmericasHealthRankings.org, Accessed 2022.

[3] Ghosh, A., Orfield, C., Schmitz, R. (December 2013), Evaluating PACE: A Review of Literature. Mathematica Policy Research Reports, Mathematica Policy Research. https://aspe.hhs.gov/sites/default/files/private/pdf/76976/PACELitRev.pdf

Medicare beneficiaries who do not meet the state's LOC requirements and can pay out of pocket for some LTSS (without enrolling in PACE).

In exploring these pathways, it quickly became apparent that implementing the first two at any scale would first require a solution that ensures Part D costs are affordable for Medicare-only PACE participants -- i.e., that are equivalent to costs offered by PDPs in the Part D marketplace. To implement the third strategy, Altarum worked with Huron Valley PACE to design LTSS services packages that could be offered to Medicare beneficiaries living in the community who, based on an assessment, agreed to purchase LTSS on an a la carte, monthly, basis. This initial Huron Valley work on market analysis, appropriate pricing, and design of LTSS services packages was substantially advanced in a subsequent project conducted for a California-based PACE organization, St. Paul's Senior Services.

This BIPA 903 waiver was written to provide Huron Valley PACE Medicare-only participants the option to select a local Part D PDP, instead of being forced to pay unreasonably high premiums for their pharmaceutical coverage through the PACE Part D plan.

Proposed Solution #1: The Waiver Approach

To bring the Part D cost issue to the attention of federal policymakers and decision-makers, Altarum and Huron Valley developed an actuarially sound PACE waiver proposal for submission to CMS in March 2018. This waiver request proposed to allow Medicare-only participants to obtain their pharmaceutical coverage through a PDP, with Huron Valley serving as an intermediary and making on behalf of these participants to the PDP.

Under the waiver as submitted, Huron Valley PACE proposed to coordinate the participant's pharmaceutical coverage very closely with the PDP. Had this waiver been approved, it would have permitted Medicare-only participants in Huron Valley PACE to gain access to affordable monthly Part D premiums, to qualify for discounts during the Part D coverage gap, and to access federally subsidized catastrophic coverage -- which is predicated on payment of copays and deductibles. The cost of those copays and deductibles would have been paid by Medicare-only participants through a supplemental premium paid to Huron Valley, which would then have paid the PDP.

The Huron Valley waiver was initially denied on June 27, 2018, although no reason was provided in writing. In a subsequent oral conversation, CMS officials indicated that they were open to the idea of a waiver, flagging that the request appeared to be for a broader policy change, and that they were not convinced that the request from Huron Valley was sufficient. Subsequently, Huron Valley re-examined its waiver proposal and re-submitted on June 28, 2019, with updates to their policies and procedures to document precisely how staff would slightly adjust their operations to coordinate seamlessly with PDP-provided Part D coverage – including paying for any drug deemed medically necessary if it was not covered under the PDP's formulary.

In September 2019, CMS issued a second denial. This time, the waiver determination letter expressed concern that the pharmaceutical benefits provided by a PDP would not be as comprehensive as the PACE Part D plan, and that financial risk might be improperly transferred from the PACE Part D plan to a PDP.

Specifically, CMS summarized the request from Huron Valley as:

> *"1) a waiver of Section 42 C.F.R. 460.92(a), which requires that the PACE benefit package for all participants include all Medicare-covered items and services; and 2) a waiver of Section 42 C.F.R. 423.30(c) of the Medicare Part D regulations, which requires a Medicare Part D eligible individual enrolled in a PACE plan that offers qualified prescription drug coverage under Part D to obtain such coverage through their PACE plan.*
>
> *HVP's request states that this waiver would allow Medicare-only, Part D eligible PACE participants to obtain coverage through a local Part D Prescription Drug Plan (PDP).*
>
> *At this time, we are unable to approve this waiver request. Under sections 1894(b)(1)(A)(i) and 1934(b)(1)(A)(I) of the Social Security Act (the Act), PACE organizations are required to provide participants with all medically necessary items and services, including prescription drugs, without any limitation or condition as to amount, duration, or scope and without application of deductibles, co-payments, coinsurance, or other cost sharing that would otherwise apply under Medicare or Medicaid. Furthermore, PACE organizations are required to assume full financial risk for all services required by their participants, and under Sections 1894 (f)(2)(B)(v) and 1934 (f)(2)(B)(v) of the Act, this requirement may not be modified or waived. Allowing a PACE participant to obtain Part D prescription drug coverage from a local Part D PDP as HVP has proposed would shift financial risk for that benefit to the local Part D plan."*

Huron Valley and Altarum provided a subsequent letter in February 2020 to further explain the waiver and address CMS' concerns. The agency did not respond to this letter and declined a meeting request. For the following two years, the agency did not seek additional input or dialogue on the issue.

Proposed Solution #2: Systemwide Waiver

Altarum believes that the recent financial impact analysis undertaken with Milliman may be useful in consideration of a possible systemwide waiver based on a 2011 precedent granted under BIPA 903 by CMS. The 2011 waiver allows Medicare and VA-eligible beneficiaries to opt to receive their drug coverage through a VA (Veterans Affairs) drug plan instead of through the PACE Part D plan. If implemented, such a systemwide approach could allow *all* PACE

The BIPA 903 systemwide waiver that was granted by CMS in 2011 allows VA-eligible Medicare-only PACE participants to access an affordable VA drug plan. This waiver applies uniformly to Medicare-eligible veterans who are enrolled in PACE organizations across the country.

organizations with Medicare-only PACE participants to receive their drug coverage through a standalone PDP if they so choose, according to conditions that would be stipulated in such a waiver.

CMS's approved systemwide PACE waiver in 2011 for veterans who are Medicare-only PACE participants also came with an accompanying waiver of Section 423.458(d) -- which addresses the need to improve the coordination of Part D with the benefits offered by the PACE organization. This suggests that a similar approach could be taken to improve coordination between PACE and PDPs. Specifically, the agency could consider issuing a broad waiver across all PACE organizations enrolling Medicare-only PACE participants, using a mechanism similar to the 2011 waiver, which was granted by CMS in the form of an administrative action issued by the Medicare Drug and Health Plan Contract Administration Group.

Below, we offer a parallel systemwide waiver draft for decision-makers to consider, which is designed to resemble the 2011 waiver granted for Medicare veterans as closely as possible. Under this approach, all Medicare (non-Medicaid) PACE applicants would be allowed to use a Part D PDP instead of the PACE PDP. The 2011 CMS systemwide waiver for veterans can be found in Appendix C, and proposed parallel waiver language for Medicare-only non-VA beneficiaries is below. We believe this approach has merit for two reasons: First, CMS has approved systemwide Part D waivers for all PACE organizations on numerous occasions – see 2.3 at https://www.cms.gov/files/documaent/2021-pace-part-d-application.pdf. Second, to again note the agency's own precedent of 2011, in addition to Part D waiver authority, that waiver for Medicare veterans also employed PACE waiver authority (BIPA 903) for *all* PACE organizations that had veterans who were participants. In doing so, the agency waived the two provisions -- subsections (f)(2)(B)(ii) [*comprehensive benefits*] and (f)(2)(B)(v) [*full financial risk*] – that it has so far declined to waive for non-veteran Medicare beneficiaries.

Proposed Parallel Language for a CMS Systemwide Waiver That Could be Granted to all PACE Organizations with PACE Medicare-only Participants That Wish to Receive their RX Coverage through a PDP

The aim of this agreement is to coordinate prescription drug benefits and delivery between PACE organizations and a stand-alone PDP on behalf of Medicare beneficiaries enrolled in PACE.

Currently, Medicare-only PACE enrollees who are eligible for a Part D Standard Benefit do not have access to a Standard Part D benefit and must have a 100% drug benefit provided through the PACE organization in which they are enrolled, which means that they are not eligible for rebates at point of purchase and for federal reinsurance.

Specifically, PACE regulations at Section 460.92 require that the PACE benefit package include, among other things, all Medicare-covered items and services, including Medicare Part D prescription drug coverage. In addition, Part D regulations at CFR Part 423.30(c) require PACE enrollees to obtain their prescription drug benefits from their PACE organization. As a result, PACE enrollees who are also eligible for Standard Part D benefits currently must receive prescription drug coverage through their PACE organization. Medicare-only PACE participants are particularly negatively affected by this requirement as they are responsible for paying a significant Medicare Part D premium to the PACE organization to obtain this coverage of over $1,000 a month on average in 2022.

"It's long past time to take the brakes off of PACE and make it a program that can serve the middle class. But this won't happen until the federal government fixes the problem of aberrant and extraordinary prescription drug premiums that middle income Medicare beneficiaries have to pay for their Part D coverage to enroll in PACE. Let's take a look at the solutions on the table, choose one -- and go forward to more fully allow middle income beneficiaries to benefit from the PACE program." – Jennie Chin Hansen, former senior staff and CEO of On Lok PACE (1980-2005)

CMS understands that arrangements between PACE organizations and stand-alone PDPs would benefit Medicare-only PACE participants by facilitating coordination of their prescription drug benefits between these entities. PACE Medicare-only participants would be permitted to receive their prescriptions from a stand-alone PDP, thus relieving them of the significant PACE Part D premium obligations that currently exist.

Accordingly, we are granting PACE organizations a conditional, organization-wide waiver of Section 460.92 of the PACE regulation under the authority of Section 903 of the Benefits Improvement and Protection Act (BIPA) of 2000. This waiver will permit any Medicare-only participant in your organization who is eligible for Standard, Alternative and Enhanced Part D drug coverage to choose to receive their prescription drug coverage through a stand-alone PDP and avoid paying the Medicare PACE Part D premium.

This waiver approval will be effective as of the date of this letter and the following provisions also will be in effect:

- *In accordance with Section 460.102(c) the PACE primary care physician will manage the PACE-eligible participants' care.*
- *The sponsor of the PDP in which a PACE beneficiary enrolls shall share claims data with the PACE organization without a need for a formal or informal request by the PACE organization.*

We are also granting PACE organizations a waiver of Section 423.30 of the Medicare Part D regulations that requires Medicare Part D eligible individuals to obtain qualified Medicare Part D benefits through their PACE organization. This waiver is being issued under the authority of Section 423.458(d) to improve coordination of PDP-provided Part D coverage with the benefits offered by the PACE organization. This waiver is offered to Medicare Part D eligible individuals not eligible for Medicaid who have access to drugs through a stand-alone PDP and voluntarily

choose to forego Medicare PACE Part D coverage.

We clarify that the waiver permitting coordination of prescription drug benefits between the PACE organization and the PDP on behalf of Medicare-only PACE participants does not extend to the coordination of additional health services.

Proposed Solution #3: The Legislative Approach

An alternative to the BIPA 903 waiver approach is Congressional legislation, which has been introduced in the House of Representatives.

The PACE Part D Choice Act (HR 4941) proposes to allow a Medicare-only PACE participant to enroll in PACE, and to choose either the 100% benefit-only PACE Part D plan, or a suitable PDP in the Part D marketplace, which offers varying benefit options: Standard Part D coverage, alternative Part D coverage, and enhanced Part D coverage. The bill calls for PACE organizations to coordinate drug orders through care planning and to work directly with all prescribers. In addition, PACE plans would exchange claims information with PDPs to monitor and manage Medicare-only PACE participants' medications. Under the legislation, the PACE plan would not collect PACE participant cost sharing.

Under either a waiver approach or the legislative approach, the Milliman-Altarum analysis shows that costs to PDPs, to CMS and drug manufacturers would rise very slightly on a one-time basis, while Part D costs would drop substantially for Medicare-only PACE participants. Medicare-only PACE participants electing a Part D PDP would gain access to drug manufacturer point-of-service rebates and federal reinsurance. To date, CMS' response to the legislative solution is not known.

In August 2021, the PACE Part D Choice Act of 2021 (HR 4941) was introduced by House Ways & Means members Reps. Earl Blumenauer (D-OR), Jackie Walorski (R-NE) and Rep. Debbie Dingell (D-MI), a senior member of the House Energy & Commerce Committee. In late September 2022, Rep. Chris Smith (R-NJ) joined as a co-sponsor. Although the proposal is bipartisan and non-controversial, to date the House bill has yet to be highlighted at a hearing and considered a priority for legislative action.

For the small group of current Medicare-only PACE participants (fewer than 200), one-year savings in 2022 associated with an option to purchase a Part D PDP total $1.7 million. It is also important to know that if there is no solution forthcoming in 2022, additional excess costs to these beneficiaries will continue to accrue in subsequent years, such that in 2023 and 2024, their financial burden would grow.

FINANCIAL IMPACT ANALYSIS

In a further effort to clarify concerns about shifting financial risk, Altarum and Milliman recently collaborated to produce a financial impact analysis. The resulting analysis, in the form of two

independent slide sets, and accompanied with an offer for a briefing, was sent to CMS officials, including CMS Chief Operating officer Jonathan Blum. On February 22, 2022, Blum emailed to express interest and appreciation, acknowledging receipt of the analysis.

In the chart below, the results in the far right-hand column demonstrate that if all currently enrolled Medicare-only beneficiaries (n= 172) were permitted to choose a PDP, one-time costs would rise only marginally in 2022 for Part D Plan sponsors, for CMS, and for drug manufacturers. By comparison, savings for Medicare-only PACE participants opting for a Part D PDP would be highly significant.

As noted by Milliman principal Frank Kopenski in the slide deck prepared for Congressional and Executive Branch staff, "it is only the existing PACE MO participants (less than 200), who create a cost shift to other financial stakeholders if they opt out of the PACE prescription drug benefit." In other words, if all of the Medicare-only PACE participants were suddenly shifted to a PDP, the impact on CMS, and across multiple Rx manufacturers and PDPs, would be quite minor, as shown in the far right-hand column below.

2202 Stakeholder Financial Impact Analysis
(Prepared by Milliman, Frank Kopenski, Jr., ASA, MAAA)
Table 1

Benefits Available:	**PACE MO Eligible (Not enrolled in PACE)**	**PACE MO Eligible (Enrolled in PACE)**	**Part D Option Cost Impact**	**Assume 200 MO Enrolled in PACE**
Standard Part D	Yes	No	N/A	N/A
Equivalent Alternative	Yes	No	N/A	N/A
Enhanced Alternative	Yes	No	N/A	N/A
100% Drug Coverage	Unlikely	Yes	N/A	N/A
Participant Estimated Average Cost PMPY:				
Benefit Annual Cost Sharing	$2,256.48	$0.00	$2,256.48	
Benefit Annual Premium	$400.44	$11,398.80	($10,998.36)	
Total Out-of-Pocket	$2,656.92	$11,398.80	($8,741.88)	($1,748,376)
CMS Estimated Average Cost PMPY:				
Federal Reinsurance	$2,186.40	$0.00	$2,186.40	
Premium Subsidy	$387.46	$2,041.69	($1,654.23)	
Total CMS Cost	$2,573.86	$2,041.69	$532.17	$106,434
Drug Manufacturer Estimated Cost PMPY:				
Coverage Gap Direct Rebates	$1,281.28	$0.00	$1,281.28	
CMS and Part D Sponsor Rebates	$2,358.37	$531.61	$1,826.75	
Total Manufacturer Cost	$3,639.65	$531.61	$3,108.03	$621,607
Part D Sponsor Average Cost PMPY:				
Premium Shortfall	$1,622.08	$0.00	$1,622.08	
Total Part D Sponsor Cost	$1,622.08	$0.00	$1,622.08	$324,417

Sources: 2022 CMS published national average Medicare Part D statistics and 2022 average PACE MO Part D bid results. Reproduced from Milliman Power Point presentation for Congressional Staff.

The two charts below illustrate the marked differences in who pays what, and when, for Part D coverage. The first chart shows the responsibilities of all stakeholders – beneficiaries, drug manufacturers, Part D plan sponsors and CMS – for Medicare beneficiaries who are *not* enrolled in PACE, but who are eligible for PACE. The second chart depicts in red the changes in Part D stakeholder responsibilities for Medicare beneficiaries who *are* enrolled in PACE.

Stakeholder Responsibility (PACE Eligible Medicare Eligible Member Not Enrolled in PACE)
(Prepared by Milliman, Frank Kopenski, Jr., ASA, MAAA)
Table 2

	Member	Drug Manufacturer	Part D Plan Sponsor	CMS
Part D Benefit Cost:				
Deductible	Yes	No	No	No
Initial Coverage	Yes	No	Yes	No
Coverage Gap	Yes	Yes	Yes	No
Catastrophic Coverage	Yes	No	Yes	Yes
Manufacturer Plan Rebates	No	Yes	No	No
Administrative Cost	No	No	Yes	No
Profit Margin	No	No	Yes	No
Part D Benefit Funding				
Part D Benefit Funding	Yes	No	Yes	No
CMS Subsidized Premium	No	No	Yes	Yes
Enhanced Benefit Member Premium	Maybe	No	Maybe	No

Reproduced from Milliman Power Point presentation for Congressional Staff.

Stakeholder Responsibility (PACE Eligible Medicare Eligible Member Enrolled in PACE)
(Prepared by Milliman, Frank Kopenski, Jr., ASA, MAAA)
Table 3

	Member	Drug Manufacturer	Part D Plan Sponsor	CMS
Part D Benefit Cost:				
Deductible	No	No	Yes	No
Initial Coverage	No	No	Yes	No
Coverage Gap	No	No	Yes	No
Catastrophic Coverage	No	No	Yes	No
Manufacturer Plan Rebates	No	Yes	No	No
Administrative Cost	No	No	Yes	No
Profit Margin	No	No	Yes	No
Part D Benefit Funding				
Part D Benefit Funding	Yes	No	Yes	No
CMS Subsidized Premium	No	No	Yes	Yes
Enhanced Benefit Member Premium	Yes	No	Yes	No

Values denoted in red represent differences from Table 2.
Reproduced from Milliman Power Point presentation for Congressional Staff.

Prior to this fiscal impact analysis, the PACE Part D dilemma had receded into the background of the federal policy landscape. It is our hope that going forward, it will provide renewed impetus for recognizing that this issue is an inadvertent and correctable policy error. Taking rapid action to correct the artificially inflated premiums that Medicare-only PACE participants are forced to pay each month will encourage more PACE enrollment on an ongoing basis. We have offered several ways to make the necessary technical adjustments to permit Medicare beneficiaries to be able to choose an affordable Part D plan and to avail themselves of PACE's highly coordinated services *before* they spend down to Medicaid. These Medicare beneficiaries would need to be willing and able to pay the cost of the PACE Medicaid capitation applicable in their state, which in 2020 averaged $4,141 per participant per month.[4]

"As a former PACE physician and Medical Director, I know how well this model of care works for complex older adults. Millions more Americans are going to need this type of care, and we need all options to be available. The Part D problem that has long stymied PACE enrollment is a technical error that we can all work together to solve. The status quo of asking Medicare beneficiaries to pay 20-fold more in monthly premiums than they should is a serious problem, and there is bipartisan support for solving it." – Robert Schreiber, National Medical Director of Care Model Strategy, myPlace Health

FINANCIAL ADVANTAGES TO SOLVING THE PACE AND PART D DILEMMA

According to Milliman's Kopenski, the 2022 stakeholder financial impact can be summarized as follows:

- CMS and drug manufacturers have a large stake in the drug benefit costs;
- The Part D plan sponsor, on average, does not receive enough benefit funding (i.e., revenue), from the individual participant to compensate for the PACE eligible beneficiary drug cost;
- The CMS premium subsidy, while risk adjusted, is often not adequate to cover the above average PACE participant drug spend;
- Financial impact of 200 current PACE enrollees selecting a local Part D plan:
  Drug manufacturers: 200 x $3,108.03 ~ $621,600
  CMS: 200 x $532.17 ~ $106,000
  Part D plan sponsor: 200 x $1,622.08 ~ $324,000
- Given the large number of drug manufacturers and plan sponsors in the Medicare Part D market, the impact of 200 PACE MO participants on any one entity is very small.
- The fact that this is solvable in multiple ways is good news.

[4] NPA Internal Data

NO DOWNSIDES TO RESOLVING THE PACE AND PART D DILEMMA

It can be fairly argued that Medicare beneficiaries who are enrolled in PACE today are being substantially overcharged for their Part D coverage by virtue of not being permitted to access to a reasonably priced Part D benefit, as intended by the Medicare Modernization Act of 2003. The conflict between PACE and Part D is traceable to 2006, when Medicare Part D regulations were finalized for the Medicare Modernization Act of 2003. At that time, a decision was made that PACE programs would offer their own versions of Part D plans as the only choice for Medicare-only participants. Failure to solve the PACE Part D dilemma will strand and sideline PACE as a viable option for the rapidly growing pre-dual Medicare population.

Outside of PACE, all Medicare beneficiaries receive substantial cost assistance to make their prescription drug coverage affordable from drug manufacturers and CMS, via point-of-service drug rebates, federal reinsurance, and premium subsidies. In contrast, Medicare-only PACE participants are denied this cost assistance. Consequently – and uniquely among all Medicare beneficiaries -- Medicare-only PACE participants are saddled with exorbitantly high costs for their Part D coverage. This is reflected in the data assembled by NPA for a Part D Choice Case Study (see Table 4 below). The most recent data are available in an issue brief prepared by NPA in Appendix B. What follows, on the next page, is an illustrative excerpt:

Comparing 2021 Average PACE Prescription Drug Plan Costs, Compared to 2021 Medicare Part D Standalone Prescription Drug, for a Medicare-Only Beneficiary in FFS Medicare Taking 10 Prescription Drugs

Table 4

	Monthly Premium	Annual Deductible	Annual Estimated Cost-Sharing Responsibility at Preferred Pharmacy	Total Annual Patient Out of Pocket (Premium + Deductible + Cost-Sharing)	All Drugs on Formulary?	Any Drug Restrictions?	Star Rating (out of 5, with 5 being best)
PACE Part D Plan National Average	$907.76	$0.00	$0.00	$10,893.12	Y	N	**n/a**
SilverScript Choice PDP	$26.70	$380.00	$0.00	$700.40	Y	Y	**3.5**
Humana Basic Rx Plan PDP	$27.90	$445.00	$364.44	$1,144.24	Y	Y	**3.5**
Express Scripts Medicare-Value PDP	$53.00	$445.00	$285.00	$1,366.00	Y	Y	**3.5**
AARP MedicareRx Preferred PDP	**$83.40**	**$0.00**	**$804.96**	**$1,805.76**	**Y**	**Y**	**3.5**

Annual PACE Plan Costs at Top, Remainder Sorted by Lowest Annual Total Participant Out of Pocket for All Plans Available in Zip Code.

The chart above makes the following assumptions:

- *Participant lives in zip code 22314;*
- *30-day supply of each drug at the dosages and frequencies listed below;*
- *Drugs would be purchased from one of these local retail pharmacies, whichever one was considered to be in network, preferred by each plan, and offered the cheapest monthly total out of pocket drug cost; and*
- *The pharmacies used for this chart are CVS Store #1086, Harris-Teeter Store #398 and Walgreens #12359.*

Drug List:

- *Simvastatin 20mg, 1 x day*
- *Sertraline HCL 100mg, 1 x day*
- *Lisinopril 10mg, 1 x day*
- *Carbidopa/Levodopa 25-100mg, 3 x day*
- *Furosemide 40mg, 1 x day*
- *Escitalopram Oxalate 10mg, 1 x day*
- *Levetiracetam 500mg, 2 x day*
- *Finasteride 5mg, 1 x day*
- *Meclizine HCL 25mg, 1 tablet as needed, with a maximum of 10 tablets per 30 days*
- *Gabapentin 300mg, 3 x day*

NEXT STEPS TO DRIVE TOWARD A FULL SOLUTION

Even as we continue to focus on making a case for solving the Part D dilemma, Altarum continues to broaden our focus on PACE as a highly effective model of coordinated care and a well-established program that has valuable infrastructure (e.g., a center and transportation that can be repurposed), an interdisciplinary team, and the agility to undertake rapid adaptation and innovation. In a project funded by the Agency for Healthcare Research and Quality, we are closely examining the ability of PACE during COVID-19 to pivot and focus more on delivering home-based services and telehealth, to shift staff roles, and to meet the changing needs of frail participants (many of whom could not leave their houses) using creative modalities. We are analyzing these factors in the context of comparing PACE outcomes and those of comparable Medicare fee-for-service (FFS) beneficiaries.

> *"For Medicare beneficiaries able to pay for their own care who are interested in remaining living in their homes, rather than in nursing homes, PACE is not only an affordable service option but also includes and fully coordinates all Medicare and all long- term services and supports. However, the Part D benefit designed for PACE is significantly more costly than alternative Part D options, creating a barrier for non-Medicaid eligible seniors wishing to enroll in PACE." – Shawn Bloom, President and CEO, National PACE Association*

Throughout the Rx Foundation project, Altarum has made gradual strides in moving PACE forward into a position of greater visibility for policymakers, stakeholders and other decision-makers at both the federal and state levels. We presented many of these discussion points during a comprehensive seminar in June 2021. The seminar included live and recorded presentations from Rep. Debbie Dingell and Sen. Bob Casey, federal staff from the House Ways & Means Committee and other panels, and CMS, along with state officials from Massachusetts and California, PACE leaders from across the country, and numerous national experts.

Today, only a tiny fraction of older Americans who are Medicare beneficiaries and could benefit from PACE are being reached by the program. Ninety percent of current PACE participants are dually eligible individuals; 9% are Medicaid-only; and as discussed earlier in this report, well under 1% are Medicare-only. Before PACE can be a viable option for the Medicare population, the Part D cost barrier must be addressed.

It is important to note that the range of possible future Part D reforms now being discussed by Congress would not touch the Medicare-only PACE population. As noted by Milliman's Kopenski in the financial impact analysis, "potential future Part D benefit changes, such as those under discussion and listed below, are unlikely to materially impact the magnitude of the financial stakeholders' cost shift…for 2022, [although] the actual values may change for each stakeholder depending upon the redesign."

The Milliman slide lists some of the key possible reforms:

- A hard out-of-pocket cap ($2000-$3500 range in 2024);
- Reducing reinsurance to ~20%;
- Elimination of the coverage gap phase;

- Moving manufacturer liability to the catastrophic phase (and potentially Initial Coverage Corridor); and
- Changes to drug formulary requirements.

It is our hope that the solutions outlined in this report can be further refined, shaped and taken forward under administrative authority, or approved by Congress as a technical, non-controversial legislative fix in 2022.

Appendix A

The literature documents a range of positive outcomes associated with the PACE program, including evidence of:

Fewer Hospitalizations:

Segelman, M., Szydlowski, J., Kinosian, B., McNabney, M., Raziano, D. B., Eng, C., van Reenen, C., & Temkin-Greener, H. (2014). Hospitalizations in the Program of All-Inclusive Care for the Elderly. *Journal of the American Geriatrics Society*, *62*(2), 320–324. https://doi.org/10.1111/jgs.12637

CONCLUSIONS: PACE enrollees experienced lower rates of hospitalization, readmission, and PAH than similar populations. Variations in hospitalization rates between PACE sites suggest opportunities for quality improvement.

Wieland, D., Lamb, V. L., Sutton, S. R., Boland, R., Clark, M., Friedman, S., Brummel-Smith, K., & Eleazer, G. P. (2000). Hospitalization in the Program of All-Inclusive Care for the Elderly (PACE): Rates, concomitants, and predictors. *Journal of the American Geriatrics Society*, *48*(11), 1373–1380. https://doi.org/10.1111/j.1532-5415.2000.tb02625.x

CONCLUSIONS: Overall, short-term hospital utilization among PACE participants is low in contrast with that for other older and disabled populations. Participant predictors of hospitalization in PACE are generally consistent with other studies in older clinical and community populations. Both utilization and risk vary considerably across PACE sites, independent of participant-level risk factors, hence suggesting that further investigation is required to study PACE's management of acute illness and hospitalization decisions. Critical to maintaining PACE's success is an understanding of the independent impact of the organization and the environment of health care on this management.

Improved quality for certain aspects of care:

Beauchamp, J., Cheh, V., Schmitz, R., Kemper, P., & Hall, J. (n.d.). The Effect of the Program of All-Inclusive Care for the Elderly (PACE) on Quality. In *Mathematica Policy Research Reports* (b15f567862b840d9ac9bac681301d1d4; Mathematica Policy Research Reports). Mathematica Policy Research. Retrieved March 3, 2022, from https://ideas.repec.org/p/mpr/mprres/b15f567862b840d9ac9bac681301d1d4.html

CONCLUSIONS: Overall, the results indicate that PACE improved health management outcomes, increased preventive care, and reduced hospital use. PACE participants also increased nursing home use but we caution that this increased use should not be interpreted as a negative outcome—as short-term nursing home stays may indicate more appropriate use of services.

We also found limited evidence that PACE participants had better self-reported health status; the same levels of functioning, and fewer depressive symptoms than HCBS participants. But PACE participants also had more behavioral incidents. Finally, both PACE and HCBS participants were highly satisfied with their medical and personal care, and PACE participants were just as satisfied as HCBS participants with their quality of life, medical care, and personal care.

Less institutional care:

Fazio, S., Pace, D., Flinner, J., & Kallmyer, B. (2018). The Fundamentals of Person-Centered Care for Individuals With Dementia. *The Gerontologist*, *58*(suppl_1), S10–S19. https://doi.org/10.1093/geront/gnx122

CONCLUSIONS: What this literature review establishes is that there is nothing clear-cut about demonstrating scientific evidence for complicated, individualized, psychosocial interventions such as person-centered care. Overall, the research has limitations including sample sizes, varied interventions within person-centered care models and finally, a paucity of funding and incentives for psychosocial research. Most certainly, more research is needed to continue to understand how to effectively measure person-centered care, what elements are required to make a difference and how does all of this translate into everyday care delivery practices.

Falvey, J. R., Gustavson, A. M., Price, L., Papazian, L., & Stevens-Lapsley, J. E. (2019). Dementia, Comorbidity, and Physical Function in the Program of All Inclusive Care for the Elderly. *Journal of Geriatric Physical Therapy (2001)*, *42*(2), E1–E6. https://doi.org/10.1519/JPT.0000000000000131

CONCLUSIONS: Ambulatory PACE participants have average levels of physical function that are dangerously close to thresholds thought to indicate vulnerability for further disability development, hospitalization, and nursing home admission. Both dementia and comorbidity burden are associated with declines in physical function, and the interaction between these risk factors is a telling indicator to functional decline in higher-level ambulatory tasks. PACE program clinicians can use this information to better identify participants at risk for limited physical function. Further research should investigate consequences of functional decline and determine optimal intervention strategies for PACE participants with functional impairments.

Chen, Liang-Yu, Ting-Jung Hsu, Li-Ju Ke, Hui-Te Tsai, Wen-Ting Lee, Li-Ning Peng, Ming-Hsien Lin, and Liang-Kung Chen. “Care for Older Adults with Dementia: PACE Day Care or Residential Dementia Care Units?” *Archives of Gerontology and Geriatrics* 93 (March 1, 2021): 104310. https://doi.org/10.1016/j.archger.2020.104310

CONCLUSIONS: PACE services significantly reduced unexpected hospital admissions of persons with dementia (PwD), facilitated the maintenance of physical independence, and improved cognitive performance and mood status. Further randomized controlled studies are needed to determine the most appropriate care model for PwD.

High levels of participant and caregiver satisfaction:

Denham, Amy C. "Community Care Alternatives for Older Adults". *Chronic Illness Care-Principles and Practice.* Springer International Publishing, T.P. Daaleman, M.R. Helton (eds.). (AG 2018 259). https://doi.org/10.1007/978-3-319-71812-5_21

CONCLUSIONS: Outcomes for PACE participants appear to be generally positive, as measured by participant and caregiver satisfaction, quality of care, functional status, mortality, and health service utilization. Understanding the effectiveness of the PACE model, however, is limited by the lack of research using randomized trials or study designs that adequately control for potential confounders. Because individuals who enroll in PACE services are likely different from individuals who are admitted to nursing homes or who enroll in other home- and community-based services (HCBS), it is difficult to find an equivalent comparison population, so our current evidence base does not fully capture how outcomes for PACE participants compare to other similar patient populations not enrolled in PACE.

Additional findings:

Ghosh, A., Orfield, C., Schmitz, R. (December 2013), *Evaluating PACE: A Review of Literature.* Mathematica Policy Research Reports, Mathematica Policy Research. https://aspe.hhs.gov/sites/default/files/private/pdf/76976/PACELitRev.pdf

CONCLUSIONS: "Several key findings emerge from this literature review regarding the design and methodological approaches of prior PACE evaluations as well as on the effectiveness of PACE in controlling spending, reducing hospitalizations and NH use, and improving quality of care and satisfaction." Among these are:

Based on evidence from studies with the strongest design, we found that PACE has no significant effect on Medicare costs, but it is associated with significantly higher Medicaid costs, with the Medicaid spending gap between PACE and matched comparison enrollees decreasing over time. Therefore, based on current evidence, we conclude that PACE does not save costs for either program, and it raises overall cost through an increase in Medicaid expenditures. However, prior findings on Medicare and Medicaid costs need to be updated, given changes to the Medicare capitation payment approach as well as variation in the Medicaid capitation rate calculations across states.

Evidence on the effect of PACE on the utilization of expensive acute and LTSS is mixed--studies with the strongest design find PACE enrollees have fewer inpatient hospitalizations than their FFS counterparts, but they appear to have higher rates of NH admission. Also, there is some evidence that program maturity is correlated with greater success in reducing hospitalization rates. Although greater care coordination in PACE could reduce enrollees' need for hospitalizations, some of these comparisons may be distorted by the substitution of short-term nursing facility stays for hospitalizations under PACE--a neglected aspect of research on the effect of PACE on NH utilization.

There is some evidence that PACE improves certain aspects of care quality--for example, those related to management of specific health issues such as pain; also, based on a single study with a strong research design, it appears that PACE enrollees have lower mortality rates over the period 1-4 years after enrollment, a finding corroborated by results from two other studies with a relatively weak design.

Although PACE participants are satisfied with their medical and personal care, there is insufficient evidence as to whether satisfaction and quality of life actually improves under PACE or not, since the only study with a moderate to strong rating found few significant differences between PACE and the HCBS comparison group in patient satisfaction and quality of life.

Harootunian, L., Salyers, E., O'Gara, B., Wu, K., Hayes, K., Hoagland, W. G. (September 2021). *Bipartisan Solutions to Improve the Availability of Long-term Care*. Bipartisan Policy Center. https://bipartisanpolicy.org/download/?file=/wp-content/uploads/2021/09/BPC_Health_Long_Term_Care_RV4-min.pdf

CONCLUSIONS: No single politically viable solution exists to address the nation's LTSS needs. Bipartisan policy solutions that improve upon the LTSS delivery system could help to address the growing demand for these critical services in the United States. BPC's recommendations have the potential to expand access to LTSS for individuals with LTSS needs across a range of income levels, through public and private health insurance programs. We encourage long-term care planning by improving public education, while also providing some financial relief for unpaid family caregivers who remain critical providers in the LTSS delivery system. We hope these recommendations advance discussions among policymakers to support bipartisan policy solutions that improve access to LTSS for children, adults, and seniors with functional or cognitive impairment.

Appendix B

Altarum Medicare Part D for PACE Participants Without Medicaid slides

Milliman Medicare PACE Part D for PACE Participants Without Medicaid slides

Leadership Council on Aging Organizations (LCAO) PACE Part D slides

PACE Seminar and *resources*

HR 4941-PACE Part D Choice Act of 2021

NPA PACE Part D Choice Issue Brief and Part D Pricing Study

Huron Valley PACE Combined BIPA 903 and Part D Waiver Request and Letters of Support

PACE and Part D Issue Brief

Appendix C

2011 CMS WAIVER GRANTED TO ALL PACE ORGANIZATIONS ENROLLING VETERANS WHO ARE MEDICARE-ONLY PACE PARTICIPANTS

Department of Health and Human Services
Centers for Medicare and Medicaid Services
Center for Medicare
7500 Security Boulevard, Mail Stop C4-21-26
Baltimore, Maryland 21244-1850

Medicare Drug and Health Plan Contract Administration Group

July 28, 2011

Dear _____,

On January 7, 2010, the Veterans Health Administration {VHA) awarded funds to VA Medical Centers (VAMs) to pursue and implement service agreements with PACE Organizations to coordinate prescription drug delivery between the VA and PACE on behalf of veterans enrolled in PACE. As described in a Department of Veterans Affairs memorandum to its Network Director dated November 4,2009, Fiscal Year (FY) 2010 VHA funds will be awarded and renewed, given acceptable 2010 progress reports through FY 2010. It is the expectation that projects will have demonstrated their worth and will continue in FY 2012 and beyond, The VA Medical Centers (VAMC) and PACE organizations with which they will enter into agreements are identified below:

Table Redacted

Currently, PACE enrollees who are eligible for VA benefits do not have access to the VA

Prescription drug benefit. Specifically, PACE regulations at 42 C.F.R. Part 460.92 require that

the PACE, benefit package includes, among other things, all Medicare-covered items and services, including Medicare Part D prescription drug coverage. In addition, Part D regulations at42 C.F.R, Part 423.30(c) require PACE enrollees to obtain their prescription drug benefits from their PACE organization. As a result, PACE enrollees who are also eligible for VA benefits

currently receive prescription drug coverage through their PACE organization. Medicare-only PACE veterans are particularly affected by this requirement as they are responsible for paying a significant Medicare Part D premium to the PACE organization to obtain coverage.

We understand that the proposed arrangements between the VA and PACE would benefit veterans by facilitating coordination of prescription drug benefits between the VA and Medicare. PACE veterans would be permitted to receive their prescriptions from the VA, thus relieving them of the Medicare Part D premium obligations that currently exist.

As your organization is one of the PACE organizations that have been selected to enter into an agreement with a VAMC we are granting your organization a conditional, organization-wide waiver sf

460.92 of the PACE regulation under the authority of section 903 of the Benefits Improvement and Protection Act (BIPA) of 2000. This waiver will permit any participant in your organization who is eligible for VA drug coverage to choose to receive their prescription through the VA and avoid paying Medicare Part D premiums.

This waiver approval will be effective as of the date of this letter and upon execution of a provider agreement between the VAMC listed above and your organization that shall include the following provisions that have been prior approved by CMS:

- In accordance with 460.102(c) the PACE primary care physician will manage the VA-eligible participants' care.
- Prescriptions will be ordered by the PACE primary care physician in accordance with the individual's care plan. The VA shall dispense the prescription as ordered by the PACE primary care physician and not impose step therapy, prior authorization or other such cost saving mechanisms.
- If the prescription is not available from the VA formulary, the prescription shall be provided by the PACE organization.
- In the event of any future non-renewal or termination of the VAMC/PACE provider agreement, VA-eligible PACE participants who have elected to receive their drug coverage through the VA must be notified, at a minimum, 60 days prior to the nonrenewal or termination. At such time, VA-eligible PACE participants shall also be notified that they will be required to receive their prescription drug coverage through the PACE organization. In the absence of the VA/PACE prescription drug provider agreement that permits VA-eligible PACE participants to receive prescription drug coverage from the VA, these individuals may become responsible for paying the Medicare Part D premium depending on Medicare/Medicaid eligibility status.

The terms and conditions of these provisions may not be altered without prior written authorization of CMS, the state administrating agency and the VA.

We are also granting your organization a waiver of 423.30(c) of the Medicare Part D regulations that requires Medicare Part D eligible individuals to obtain qualified prescription drug benefits through their PACE organization. This waiver is being issued under the authority of 423.458(d) to improve coordination of Part D with the benefits offered by the PACE organization. This waiver is authorized to facilitate offering PACE benefits to VA-eligible individuals who have access to drugs through the VA and voluntarily choose to forego Medicare Part D coverage.

PACE organizations participating in this waiver will be required to review their Monthly Membership Report (MMR) from CMS on a monthly basis and promptly identify and report to CMS the PACE members enrolled subject to this waiver each month. This reporting will allow CMS to deduct the Part D subsidy payments from the PACE organization's next monthly payment for those individuals who elect to receive prescription drugs through the Veterans Administration. (INSERT PO NAME) must submit this information each month no later than the Plan Data Due Date on the MARx Monthly Schedule. The current schedule may be obtained by going to the MAPD Help Desk website (www.cms.gov/MAPDHelpDesk) and following the link on the left-hand side of the page to the Plan Communications User's Guide. The schedule is located in Appendix C of the Guide.

The PACE organization will first be required to establish a Point of Contact (POC) for the required monthly reporting. Please email the following information to CPC_DPO@cms.hhs.gov, with "PACE – VA POV" in the subject line:

- Name of PACE Organization
- Contract Number
- POC Name
- POC Email Address
- POC Phone Number

Following receipt of POC information, CMS will provide details to the designated POC for the required monthly reporting. A spreadsheet format will be provided. The PACE organization will locate the following information on the MMR for the PACE participants who have elected VA coverage, complete and email the spreadsheet to CPC_DPO@cms.hhs.gov, with "PACE _ VA Payments for Payment Month mm/yyyy" in the subject line. Item numbers below refer to the Monthly Membership Detail Data Plan record layout (see Plan Communications Users Guide, Appendix E.9):

- Contract Number (#1)
- PBP Id (#45)
- HICN (#4)
- Last Name (#5)
- Sex (#7)
- Date of Birth (#8)
- FIRST Payment Month (#3)
- Total Part D Payment (#77)

The monthly spreadsheet must contain ALL applicable applicants with payments or adjustments on that month's MMR, including those reported in prior months along with new participants electing VA coverage. The FIRST Payment Month will indicate which participants are new (because the date in the spreadsheet detail line will match the date in the subject line of the email).

The Part D payments for the participants electing VA coverage will be deducted form the next month's payment. This deduction will include the net amount of prospective Part D payments and adjustments appearing on the MMR applicable to the VA coverage election period. The total deduction for all participants will be reported on the Plan Payment Report under Section 6, CMS Adjustments. It will not be reported on the MMR.

We clarify the applicability of this waiver permitting coordination of prescription drug benefits between the PACE organization and the VA on behalf of VA-eligible PACE participants does not extend to include the coordination of benefits of additional health services between the PACE organization and the VA.

Please note that these waiver approvals are contingent upon a signed 3-party PACE program agreement. In addition, these arrangements will be reviewed during monitoring visits in the future. Should it be noted at that time that an arrangement is not in fact consistent with the terms of the waiver approvals, we will reconsider your approval for the related waiver or waivers.

Subject Redacted will be responsible for evaluating the impact of these waiver approvals have on policies, procedures, and marketing materials. Updates to these affected documents should be submitted to CMS and the State within 90daysof this approval letter.

If you have further questions, please contact John Hebb at 410-786-6657 for BIPA 903 waiver issues, Deborah Larwood at 410-786-9500 for Part D waiver issues or William Buckstein at 410-786-7477for payment issues.

Sincerely,
[signature]

Kathryn Coleman
Director, Division of Medicare Advantage Operations
Medicare Drug Plan and Health Plan Contract Administration Group

Christian Bauer
[signature]

Director
Division of Drug Plan Policy and Quality

cc:
CMS Regional Office
CMS Central Office
State Administering Agency