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For-Profit PACE Programs: Harbinger of the Future?

By J. Mark Waxman

I. Introduction

The Program of All-Inclusive Care for the Elderly (PACE) is a benefit program provided by the federal government through the Centers for Medicare & Medicaid Services (CMS), geared toward the care of frail, elderly individuals.[1] The program model centers around the belief that it is best to deliver and provide seniors' chronic care needs within their respective communities, as opposed to within a nursing home.[2] The model was initially developed in the 1970s, beginning with one adult day-care center in San Francisco. Today, there are 114 PACE programs operating in 32 states.

Historically, only not-for-profit organizations could pursue sponsorship of PACE programs. In 2007, CMS began developing a study on the effects of for-profit programs participating in PACE, the results of which were published in a May 19, 2015, report to Congress. This article provides an overview of the PACE program, explores CMS's report and its potential consequences, and offers guidance as to the future of for-profit organizations' participation in PACE programs.

[1] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pace111c01.pdf.

[2] http://www.npaonline.org/website/article.asp?id=12&title=Who,_What_and_Where_Is_PACE?.

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II. The Historical Development of the PACE Program

The PACE care-providing model of community-based medical services first became the focus of federal and state governments in the 1970s. A community in San Francisco heavily populated by families whose elders had immigrated from Italy, China, and the Philippines had an urgent need for long-term and affordable care services for the elderly. William Gee, a public health dentist, took it upon himself to better the service offerings available to elderly individuals in the Chinatown-North Beach community. Along with numerous community leaders and medical professionals, Gee established a not-for-profit organization called On Lok Senior Health Services, with the goal of creating community-based care systems. The chronic care system that On Lok sought to offer combined individuals' housing needs and all necessary medical and social services into one comprehensive service offering.

On Lok Senior Health Services in San Francisco enrolled the frailest of the community's elderly who most required long-term care. In 1973, On Lok opened its first adult day center in San Francisco, and almost immediately began receiving Medicaid reimbursements for its offered services. By 1975, On Lok added a social day care center, as well as in-home care, home-delivered meals, and housing assistance to its program. On Lok's ultimate goal was to provide, through one central hub, all of an elderly individual's needs—both medical and social. By 1978, the On Lok model of centralized elderly care grew close to its goal, as the program by then included complete medical care and social support to nursing home-eligible individuals.

On Lok's program model piqued the government's interest. In 1979, On Lok received a four-year grant from the Department of Health and Human Services (HHS) to continue developing a consolidated model of care delivery to individuals with chronic care needs. Within the next few years, the department allowed On Lok to experiment with a new financing system for the program, one that would pay the program a fixed amount each month for every participating person. In 1987, On Lok received from HHS a number of health care access-focused private foundation endowed grants in support

of the program's efforts to replicate the model in 10 organizations across the country. Federal legislation also extended On Lok's financing system to include its 10 replicas. These 10 organizations duplicated On Lok's service delivery and funding model.

These programs were first recognized by the formal title ''Program of All-Inclusive Care for the Elderly'' in 1990, which was also the year the first PACE programs received Medicare and Medicaid waivers to operate. In 1994, On Lok established the National PACE Association to advance the efforts of PACE programs across the country, seeking to coordinate and provide much-needed preventive, primary, acute, and long-term care services to the elderly so as to allow the individuals to continue living in their respective communities. At this point in time, 11 PACE organizations were operating out of nine states. Just two years later, this number almost doubled, with 21 PACE programs operating in 15 states.

The Balanced Budget Act of 1997, Pub. L. No. 105–33§ § 4801–02, declared the PACE model a permanently recognized provider type under both the Medicare and Medicaid programs. By 2000, 30 PACE programs were operating in 19 states. In 2001, CMS recognized the first PACE provider as a full, permanent part of the Medicare and Medicaid programs. The first decade of the 21st century saw great expansion of the PACE program. In 2006, Congress awarded grants of $15,000 to 15 organizations to encourage rural PACE expansion. By 2010, the number of PACE programs increased to 75 organizations operating in 29 states and today, there are 114 PACE programs operating in 32 states.

III. Statutes and Regulations Governing PACE

A. Federal Regulations and Legislation

i. Legislative History

The Balanced Budget Act of 1997 (BBA) first authorized the PACE model as a permanent Medicare program element by adding § 1894 to Title XVIII of the Social Security Act (SSA), which addressed Medicare payments to, and coverage of benefits under, PACE. The BBA also authorized PACE as a Medicaid state program by adding § 1934 to Title XIX of the SSA.

SSA Sections 1894 and 1934 differ in their treatment of the process by which not-for-profit and for-profit organizations may enter the PACE program. The SSA allows for private, for-profit organizations to participate in the PACE program only if they are granted demonstration waivers by the secretary of health and human services. The waiver application process for for-profit organization is described in Sections 1894(h) and 1934(h), which state that the secretary may grant waivers, on a case-by-case basis, from PACE's for-profit entity exclusion. This waiver allows for-profit organizations to participate in the PACE program solely through the program's demonstration project, which was specifically created for for-profit organizations. The waiver demonstration project capped for-profit participation at 10 for-profit sites. Not-for-profit organizations, on the other hand, are not subjected to such waivers and could directly apply to become a PACE program without any waiver requirements.

The BBA specifies that while participating in the PACE program, both for-profit and not-for-profit organizations must meet all the main requirements set forth in the PACE regulations. The main requirements are in three areas: (1) operation; (2) comprehensive benefits; and (3) transition requirements.

ii. Federal Regulations

The Code of Federal Regulations sets forth the regulations governing the PACE program, including the requirements for both the organizations seeking to participate in PACE programs, as well as for the individuals seeking PACE program benefits.[3] Specifically, the regulations discuss eligibility standards for both the organizations and the individuals seeking to get involved in PACE. The regulations list a number of requirements for entities submitting an application to become a PACE organization, with no differentiation made between for-profit and not-for-profit organizations.[4] These include:

(1) A focus on frail elderly qualifying individuals who require the level of care provided in a nursing facility;

(2) The delivery of comprehensive, integrated acute and long-term care services;

(3) An interdisciplinary team approach to care management and service delivery;

(4) Capitated, integrated financing that allows the provider to pool payments received from public and private programs and individuals; and,

(5) The assumption by the provider of full financial risk.[5]

The regulations also state that a PACE organization must be either (1) an entity of city, county, state, or tribal government; or (2) a private, not-for-profit entity organized for charitable purposes under Section 501(c)(3) of the Internal Revenue Code of 1986.[6] Private, for-profit providers are treated separately in the federal regulations, as they would otherwise be barred from participating in PACE. For-profit providers must be granted a demonstration project waiver from the requirement that a PACE program must be one of the two entities specified in the regulations, i.e., a public entity or a private, not-for-profit entity.

B. Representative State Statutes and Regulations

The BBA provided authority for states to elect PACE as an optional Medicaid benefit. States must notify CMS that they have elected PACE as an option through a State Plan Amendment submitted to CMS by the state Medicaid agency. Thirty-two states currently are participating in the PACE program. Below is a brief discussion of PACE statutes and regulations in California, Colorado, New Jersey, and Iowa.

i. California

California's Welfare & Institutions Code governs the state's PACE program, specifying that the state Department of Health Care Services may ''enter into contracts with public or private nonprofit organizations for implementation of the PACE program and also may enter into separate contracts with PACE organizations to fully implement the single state agency responsibilities assumed by the department in those contracts . . .''[7] The statutes address entering into contracts with not-for-profit organizations, as well as separate contracts with PACE organizations. Within the state statutes, a ''PACE

[3] 42 C.F.R. § 460.
[4] *Id.* at § 460.26.
[5] *Id.*
[6] *Id.* at § 460.60.
[7] Cal. Welf. &. Inst. Code § 14593(a)(1) (West 2015).

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organization'' is ''an entity as defined in § 460.60 of Title 42 of the Code of Federal Regulations.''[8] California's PACE statutes make no reference to, and impose no restriction upon, the type of entity permitted to participate in the PACE program, and therefore, this section of the Welfare and Institutions Code allows for for-profit entry into the PACE program.

ii. Colorado

Colorado, in its Revised Statutes, sets out eligibility to participate in the state's PACE program. Colorado statutes provide that the Colorado state department will ''develop and implement a contract with any nonprofit organization providing the PACE program that sets forth contractual obligations for the PACE program, including but not limited to reporting and monitoring of utilization of services and of the costs of the program as required by the state department.''[9] As initially adopted, the PACE statute did not create a path for for-profit organizations, and specified the implementation of contracts only with not-for-profit organizations.

The Colorado General Assembly amended the applicable statutes to include all types of organizations;[10] that is, the statute now states that all ''public, private, nonprofit, or for-profit entities'' are eligible to provide PACE benefits through the PACE model.[11] The amendment to the Colorado statute also addressed the process by which a not-for-profit PACE provider may convert to a for-profit PACE provider. The conversion process consists of transmitting a conversion plan and written notice to the attorney general, no later than 60 days prior to the closing or effective date of the conversion. The attorney general, within 10 days of receipt of a conversion plan, will post the plan on its website and receive public comments about the plan. The public comments will also be available on the attorney general's website. The amended statute became effective in May 2015.

iii. New Jersey

New Jersey's statutes have included for profit and nonprofit organizations for some time. Under New Jersey Law, a PACE is a program ''operated by a public, private, nonprofit or proprietary entity, as permitted by federal law.''[12] Unlike the other state statutes discussed above, New Jersey's statutory language has, historically, allowed for the inclusion of for-profit PACE organizations, as long as such organizations can meet the requirements set out in the BBA.

iv. Iowa

Iowa's regulations do not specify which types of organizations may participate in the PACE program.[13] Instead, Iowa simply follows the process designated by CMS, requiring that a ''prospective PACE organization must receive CMS approval as a PACE organization,'' which, for Iowa, means that a ''prospective PACE organization must submit any request for waiver of federal PACE regulations to the department for initial review . . .''[14] Therefore, up until now, a for-profit organization seeking to participate in the PACE program in Iowa would have to go through the waiver request process before being eligible to participate.

IV. CMS's Congressional Report

As discussed earlier in this article, Sections 1894(a)(3)(A)(i) and 1934(a)(3)(A)(i) of the SSA require a PACE organization to be a public entity or a 501(c)(3) private, not-for-profit entity, while Sections 1894(h) and 1934(h) address the granting of a waiver of this requirement in order to demonstrate the operation of a PACE organization by a private, for-profit entity. Language was built into the BBA requiring the secretary to provide a report to Congress detailing the impact of this demonstration on quality of care and costs of services.

Mathematica Policy Research, under contract with CMS, conducted the study to address the quality of and access to care for participants in the for-profit PACE organizations, while also looking into other issues that could arise from the participation of for-profit organization in the PACE program. The study on which the final report was based was conducted in 2012-2013 and looked into the four for-profit PACE organizations in operation during the same period. One of the for-profit providers commenced operations through the demonstration in 2007, while the other three began serving beneficiaries in 2011. Mathematica also selected four not-for-profit organizations located in the same state as comparison tools.

The BBA language specifically requires the congressional report to include findings on whether any of the following four statements is true with respect to the for-profit PACE demonstration:

(1) Fewer than 800 individuals were enrolled with entities operating under demonstration project waivers (or a lesser number that the secretary may find statistically significant to make certain conclusions with respect to the findings).

(2) The population enrolled with these entities is less frail than the population enrolled with other PACE organization.

(3) Access to or quality of care for individuals enrolled with the for-profit entities is lower than access or quality for individuals enrolled with other PACE organizations.

(4) The application of the determination waivers has resulted in an increase in costs under the Medicare or Medicaid programs as compared to the costs that would have been incurred without the availability of such waivers.

Unless the secretary determines that any of the specific finding described above are true, the statutory requirement that a PACE organization be a not-for-profit entity will no longer apply.[15] The requirements are the same for not-for-profit and for-profit PACE organizations, outside of the waiver requirement. Therefore, if the for-profit exclusion were to be repealed, there would be no expected changes in operations for the organizations participating in the demonstration.

After the completion of the year-long study, the secretary determined that based upon the evidence retrieved from the four participating for-profit PACE pro-

[8] *Id.* at § 14592(a).
[9] Colo. Rev. Stat. § 25.5-5-412(2)(b) (2013).
[10] *Id.*
[11] S.B. 15-137, 2015 Legis. Serv., Ch. 163 (Colo. 2015).
[12] N.J. Stat. Ann. § 26:2H-88 (West 1998).
[13] Iowa Admin. Code r. 441-88.82(249A) (2015).
[14] *Id.* at 441-88.82(2).
[15] *See* 42 C.F.R. § 460.60.

grams and the four participating not-for-profit PACE programs, none of the four statements listed above was true. In the report, the secretary went through each of the four inquiries that the study addressed and explained why the inquiry did not apply to for-profit PACE organization. The key results and evidence supporting them, in brief, were as follows:

(1) With regard to the population size, the for-profit organizations had a total enrollment of 1,088 covered lives, which is more than the 800 lives designated in the BBA statement. At the time of the study, there were four participating for-profit providers. As of the date of the report, there were six for-profit PACE organizations. Only the first four were considered for the purposes of the report. Additionally, the sample size that was available for survey at the time of completion of the report study was sufficient to make statistically significant conclusions with respect to the second and third BBA statements.

(2) There was no statistically significant difference in frailty between the for-profit participants and the not-for-profit participants when they were compared based on classifications of increasing levels of frailty. The study examined six activities of daily living (ADLs) in order to assess relative levels of health and frailty between for-profit and not-for profit PACE participants. Respondents were classified into one of four ADL categories based upon increasing levels of frailty. Given the lack of statistical difference between participants' frailty levels, the secretary did not conclude that for-profit responders were generally less frail than not-for-profit responders.

(3) There was no systemic difference in quality of, or access to, care between participants in for-profit and not-for-profit PACE organizations. The study collected and analyzed 35 self-reported access to care and quality of care measures. Participants from both groups reported high levels of satisfaction of care. Over 90 percent of participants from the two populations were satisfied or very satisfied.

(4) Expenditures and costs were equal between for-profit and not-for-profit PACE organizations after taking into account numerous controlling factors. Costs for for-profit PACE organizations are calculated using the same methodology as not-for-profit PACE organizations. Therefore, it was quite simple to compare costs and expenditures of for-profit and not-for-profit PACE organizations.

Based upon the secretary's conclusion that none of the BBA statements was true in regard to for-profit PACE organizations as compared to not-for-profit organizations, the secretary recommended that the for-profit PACE organization exclusion in 42 C.F.R. § 460 no longer apply. The report does not mention any further CMS action required—that is, beyond CMS's determinations to Congress—to begin including for-profit organizations in the PACE program.

V. For the Future

As of May 19, 2015, the publication date of the CMS's report to Congress, for-profit entities are, at least on the federal level, no longer barred from participating in the PACE program solely due to their status as for-profit organizations. Yet, state regulations and statutes may stand in the way of CMS's recommendation coming to fruition in all the states where PACE programs are authorized, as a number of states specify that only not-for-profit organizations may participate in PACE programs. Based upon the CMS report, this restriction does not seem to be well-founded, and there appears to be little reason that those states with nonprofit-based limitations should not amend their regulations excluding for-profit entities from participating in PACE. The CMS report has established that there is not likely to be any material difference between the quality of services provided by for-profit and not-for-profit entities to elderly individuals enrolled in the PACE program. Thus, given the need for capital and the infrastructure to be a successful program, there currently is no policy reason to continue excluding for-profit entities from participating. The goal of the PACE program and other similar programs is to provide much-needed services to chronically ill individuals who might otherwise be unable to receive them.[16] The inclusion of for-profit organizations in state PACE programs will only increase such access to care. A positive, uniform state-level approach to for-profit entry to PACE would greatly enhance the program overall. Thus, the states participating in the program may be well advised to follow Colorado's lead and welcome the participation of for-profit entities by amending the applicable statutes and regulations to reflect the CMS findings and current approach.

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[16] *See* http://www.bna.com/population-concern-cms-b17179927895/ (During the ACO National Summit on June 17-19, 2015, CMS Deputy Administrator for Innovation & Quality and Chief Medical Officer Patrick Conway discussed the concept of an ACO-type model of care for chronically ill beneficiaries who are dual eligibles, i.e., qualify for both Medicare and Medicaid. He said that CMS has already begun discussions with some states and providers about the concept).

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