



## Alerts

### CMS Revises and Updates Requirements for the Programs of All-Inclusive Care for the Elderly (PACE)

July 29, 2019  
*Health Care Alert*

The Centers for Medicare & Medicaid Services (CMS) recently revised [regulations](#) (the "Regulations") for the Programs of All-Inclusive Care for the Elderly (PACE), making significant changes to ownership restrictions, compliance program monitoring and oversight requirements, staffing requirements, marketing, and participants' rights. The changes will provide greater administrative and operational flexibility for PACE organizations and includes multiple incentives for the growth and development of PACE Programs, making PACE program development a tremendous business opportunity for any health care provider organization that serves a large Medicare patient population. A brief summary is provided below of significant changes to the Regulations which become effective Aug. 2, 2019.

#### The PACE Program

PACE is an integrated delivery capitated managed care program that serves individuals who are age 55 or older, dually eligible for Medicare and Medicaid and certified by their state to need nursing home care, able to live safely in the community at the time of enrollment and live in a PACE service area. PACE programs utilize an interdisciplinary team (the "IDT") to deliver comprehensive integrated medical, social, acute and long-term care services to participants. PACE program services include adult day care physician care; home health care and personal care; prescription drugs; social services; medical specialties, such as audiology, dentistry, optometry, podiatry and speech therapy; respite care; and hospital and nursing home care when necessary.

#### Ownership Restrictions, Change of Control, and Service Area Expansion Requirements

The Regulations remove the not-for-profit requirement for PACE organizations, thereby authorizing for-profit entities to own, operate, and manage PACE organizations. The Regulations codify requirements for PACE program service area expansion applications to add a new PACE program center and/or to expand the PACE program geographic service area; and update the PACE organization change of control notice requirement from 14 days to 60 days.

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## Compliance Program Implementation and Oversight Requirements

The Regulations require PACE organizations to adopt and implement effective compliance oversight and measures that prevent, detect, and correct fraud, waste and abuse; and imposes Medicare Part D program requirements on PACE organizations. Compliance monitoring and oversight programs must include procedures for promptly investigating, responding to, and correcting compliance issues. The Regulations increase PACE organization record retention requirement from six years to 10 years, and mandate the use of a specific process for promptly responding to compliance issues, including requirements that a PACE organization conduct a timely and reasonable inquiry upon discovering evidence of noncompliance, take appropriate corrective actions in response to potential noncompliance, and implement procedures to voluntarily self-report potential fraud or misconduct to CMS and the requisite State Medicaid agency.

## CMS PACE Program Monitoring and Enforcement

The Regulations authorize CMS to impose alternative sanctions or civil monetary penalties (CMPs) for compliance deficiencies where CMS is authorized to terminate a PACE organizations' PACE agreement. CMS will conduct a comprehensive review (including on-site visits) of PACE organization compliance efforts during the initial three-year trial period. After the trial period, CMS will use technology to enhance efficiencies in monitoring by remotely reviewing PACE organization documents previously reviewed and will utilize a risk assessment to select which PACE organizations will be audited each year through site visits. The risk assessment will take into consideration the PACE organization's past performance and ongoing compliance with both CMS and state requirements; participant complaints; and access to care concerns.

## IDT Requirements

The PACE regulations specify that the IDT must be composed of at least the 11 members listed in the regulations, but now permits one individual to fulfill two separate roles if the individual meets applicable state licensure requirements and is qualified to fill each role. The Regulations provide PACE programs with more options for the format and location of IDT meetings and permits such meetings to be conducted by videoconferencing, telephone conference calls, or in-person meetings. The Regulations remove the requirement that members of the IDT must serve primarily PACE participants and permits the PACE organization to provide primary care physician services through a range of providers without having to obtain a waiver, including community-based physicians, qualified physician assistants, or nurse practitioners.

## Employee Staffing

The Regulations clarify restrictions on employees or independent contractors with prior convictions related to physical, sexual, drug, or alcohol abuse, and now permit PACE organizations to hire staff members with direct participant contact who do not have at least one year of experience working with a frail or elderly population as long as the person receives adequate training on working with a frail or elderly population.

## Marketing Agents

The Regulations allow PACE organizations to contract with agents and brokers to market PACE programs and make PACE organizations responsible for the activities of independent contractor individuals or entities who market on their behalf. The Regulations require PACE organizations to develop and implement a method to provide and document training provided to contracted individuals and entities.

## Marketing Materials

In addition, the Regulations clarify that PACE organizations are required to provide printed marketing materials to prospective and current patients in English and any other principal languages of the community, and that "principal languages of the community" are languages spoken in the home by at least 5% of the individuals in the applicable service



area.

## Marketing Restrictions

The Regulations make it clear that gifts or payments to induce enrollment are prohibited, unless the gifts are of nominal value, are offered to all potential enrollees without regard to whether they enroll and are not in the form of cash or other monetary rebates. The Regulations prohibit marketing by any individual or entity directly or indirectly compensated by the PACE organization based on activities or outcomes, unless the individual or entity has been appropriately trained on PACE program requirements.

## Participant Assessments

The Regulations clarify that initial participant assessments must be in person, completed in a timely manner after enrollment, and that the participant plan of care must be completed within 30 days of enrollment. The Regulations eliminate the participant annual assessment requirement and replace it with a semi-annual participant assessment requirement, however additional unscheduled reassessments are required for a change-in-participant status or at the request of the participant. The Regulations require mandatory attendance at the semi-annual participant assessment by the primary care provider, the registered nurse, and the social worker. Reassessments at the request of participants or designated representatives can be conducted via remote technology.

## Participant Disenrollment

The Regulations state that participants have the right to disenroll from the PACE program at any time and that such disenrollment must be effective the first day of the month following the date the PACE organization receives the participant's notice of voluntary disenrollment. Participant disenrollment for "disruptive behavior" is now only permitted if the disruptive behavior jeopardizes the patient's health or safety or the safety of others. The Regulations also require PACE organizations to take steps to ensure that their employees and contractors do not engage in any practice that would reasonably be expected to steer or encourage disenrollment of participants due to a change-in-health status.

## Conclusion

PACE program operators should carefully review the Regulations, and revise their policies and procedures, employee handbooks, and third-party vendor contracts to address changes required by the Regulations. All contracts with marketing agents or entities must be drafted in a manner that complies with applicable Federal and State laws.

Members of Hinshaw's Health Care Practice Group have significant experience advising health care providers regarding the development of PACE programs and compliance with PACE program and Medicare Part-D laws and regulations. For more information please contact Michael Dowell, Esq. at (213) 614-7341 or [your regular Hinshaw attorney](#).