

## **CMS FINALIZES NEW REGULATIONS FOR PROGRAM OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE) ORGANIZATIONS**

On June 3, 2019, the Centers for Medicare & Medicaid Services ("CMS") published revisions and updates to Part 460 to Title 42 of the Code of Federal Regulations. The requirements for the Programs of All-Inclusive Care for the Elderly ("PACE") under the Medicare and Medicaid programs ("Final Regulations") cover many regulatory requirements for PACE programs and create new compliance obligations for PACE program organization ("PACE Organization").

The PACE program is a unique model of managed care service delivery for the frail elderly, most of whom are dually eligible for Medicare and Medicaid benefits, and all of whom are assessed as being eligible for nursing home placement according to the Medicaid standards established by their respective states.

The Final Regulations address compliance programs, application and waiver procedures, sanctions, enforcement actions and termination, administrative requirements, PACE services, participant rights, quality assessment and performance improvement, participant enrollment and disenrollment, payment, record maintenance and reporting.

### **COMPLIANCE PROGRAM REQUIRED**

The Final Regulations require each PACE Organization to adopt and implement effective compliance oversight requirements, which must include measures that prevent, detect and correct non-compliance with CMS's program requirements, as well as measures that prevent, detect and correct fraud, waste and abuse. The compliance oversight program must, at a minimum, include establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with CMS requirements.

### **HIRING AND EMPLOYMENT REQUIREMENTS - PROGRAM INTEGRITY**

The Final Regulations add additional hiring and employment requirements for PACE Organizations, specifically that each PACE Organization must not employ individuals or contract with organizations or individuals: (1) if the PACE organization determines that an individual's contact with participants would pose a potential risk because the individual has been convicted of one or more criminal offenses related to physical, sexual, drug or alcohol abuse or use; (2) who have been found guilty of abusing, neglecting or mistreating individuals by a court of law or who have had a finding entered into the State nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of their property; or (3) who have been convicted of specific crimes for any offense described in section 1128(a) of the Social Security Act, which includes criminal offense relating to neglect or abuse of patients in connection with the delivery of a health care item or service.

### **SANCTIONS, ENFORCEMENT AND PENALTIES**

The current regulations authorize terminating a PACE Organization's agreement for cause in circumstances including, but not limited to, uncorrected failure to comply substantially with conditions of the PACE program or with the terms of the PACE program agreement, and inability to ensure the health and safety of participants, such as the presence of deficiencies that CMS determines cannot be corrected.

The Final Regulations grant CMS the discretion to take alternative actions in the form of sanctions or civil money penalties when CMS is authorized to terminate a PACE Organization's PACE program agreement.

### **MONITORING AND OVERSIGHT OF PACE ORGANIZATIONS**

The Final Regulations reduce the number of on-site visits after the 3-year trial period by utilizing a risk assessment to select which PACE Organizations will be audited each year. CMS will look to the PACE Organization's risk assessment to detail the PACE Organization's past performance and ongoing compliance with CMS and state requirements and indicate a PACE Organization needs to be reviewed, such as participant complaints or access to care concerns.

The Final Regulations retain the obligation that CMS conduct an onsite visit to observe the PACE Organization's operations. However, the Final Regulations afford reviewers the flexibility to conduct other portions of the review remotely. CMS noted in the comments and responses

to the Final Regulations that this should provide greater flexibility to conduct portions of the review remotely would allow CMS reviews of PACE Organizations to gain some of the same efficiencies that CMS currently achieves through the use of web-based technologies in other programs.

The Final Regulations delete the language in §460.192(b) that requires onsite review every two years and replace it with that requirement that CMS will conduct reviews of the operations of PACE Organizations as appropriate, by utilizing a risk assessment as the means of selecting which PACE Organizations will be audited each year.

#### **ADDITIONAL FLEXIBILITY FOR INTERDISCIPLINARY TEAM**

The Final Regulations make several changes intended to expand the flexibilities of the interdisciplinary team ("IDT") that comprehensively assesses and provides for the individual needs of each PACE Organization. Key provisions in the Final Regulations include permitting one individual to fill two separate roles on the IDT if the individual has the appropriate licenses and qualifications for both roles, and permitting the primary care provider that is required for each IDT to include nurse practitioners, physician assistants and community-based physicians, in addition to physicians. The Final Regulations also remove of the requirement that members of the IDT must serve primarily PACE participants.

#### **EFFECTIVE DATE**

The Final Regulations will become effective August 2, 2019.

#### **PRACTICAL TAKEAWAYS**

- Effective August 2, 2019, the Final Regulations require that each PACE Organization have a compliance program;
- PACE Organizations must have additional employee screening processes in place to check that each is reviewed and background searches occur;
- PACE Organizations should review the roles within their interdisciplinary team;
- PACE Organizations should maintain documentation of compliance with the regulations in a readily accessible format given that remote monitoring is now possible; and
- The Final Regulations now allow CMS to impose civil monetary penalties in addition to termination of the PACE Organization provider agreement.

#### **PACE ORGANIZATION COMPLIANCE PROGRAM TOOLKIT AVAILABLE**

Hall Render has developed a compliance program toolkit to assist PACE Organizations in achieving compliance with the Final Regulations. For more information about the toolkit, please contact Sean Fahey at (317) 977-1472 or [sfahey@hallrender.com](mailto:sfahey@hallrender.com).

If you have questions about this topic, please contact:

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