PUBLICATION

New PACE Rules Reduce Oversight, Increase Flexibility for Participating Organizations

July 18, 2019

For the first time since 2006, CMS has issued updated rules affecting the Program for All-Inclusive Care for the Elderly, or PACE organizations. The final rule, published in the June 3, 2019 issue of the Federal Register, finalizes a proposed rule issued in 2016 and will go into effect on August 2, 2019. PACE organizations provide community-based integrated care to frail elderly individuals who qualify for a nursing home level of care but who are still able to live in the community with support. Most participants are dual Medicare and Medicaid beneficiaries. Many of the changes in the new rules clarify existing requirements applicable to PACE organizations and codify existing guidance into regulation, while others constitute substantive changes to the program. Most notably, CMS is formally removing the regulatory requirement that a PACE organization be a not-for-profit entity. CMS also declined to formalize proposed rules related to compliance oversight of PACE organizations, citing concerns regarding the burden on the organizations, but expanded its sanction authority to include civil monetary penalties in addition to termination actions. The new regulations also offer PACE organizations increased flexibility regarding the composition of the interdisciplinary team (IDT).

Key Changes

CMS identifies several major changes related to the administration of PACE organizations.

Not-for-Profit Requirement

In its original incarnation, all PACE organizations were required to be not-for-profit entities. However, the Department of Health and Human Services (HHS) was required to conduct a study and report to Congress whether, based on the results of the study, services provided to participants by for-profit PACE organizations were meaningfully different from those provided by not-for-profit PACE organizations with regard to access and quality. If HHS did not find meaningful differences, the measure of which was codified as four specific statements that were to be determined to be either true or false, the exclusion of for-profit entities from the program would expire as of the date the report was presented to Congress. The report, dated May 19, 2015, did not find any of the statements to be true, and thus, for-profit entities became eligible to participate under the PACE authorizing statute. Based on the determination that the statutory requirement has been effectively repealed by operation of law, CMS has removed the requirement that PACE organizations be not-for-profit entities from the regulatory language, thus allowing for-profit companies to participate in the program.

PACE Interdisciplinary Team

Current regulations require that each PACE organization provide care under the oversight of an interdisciplinary team (IDT) that includes 11 different individuals who "primarily serve" PACE participants. The requirement that IDT members "primarily serve" PACE participants means that PACE organizations generally directly employ a physician who has responsibility for all of the PACE participants at the PACE center and who does not see other patients in the community. Because the IDT requires the participation of a "primary care physician," nurse practitioners and physician assistants are not currently able to fill that role.

Under the new rules, a single individual may fill two roles on the IDT if the individual is appropriately licensed and qualified to do so. The composition of the IDT itself now requires the participation of a "primary care provider" rather than a primary care physician, thus allowing nurse practitioners and physician assistants to fill that role, consistent with state law. Additionally, CMS removed the requirement that IDT members "primarily serve" PACE participants, permitting community-based providers to serve as participants' primary care provider and serve on the IDT.

Governing Body and Compliance Oversight

The new regulations clarify that the governing body of a PACE organization is legally and financially responsible for the operation of the organization, including its quality improvement programs. However, CMS declined to formalize requirements related to compliance oversight, for which the governing body of the PACE organization would also have been responsible. CMS stated that for those PACE organizations offering prescription drug benefits under Part D, requirements for monitoring and oversight of Part D would apply. However, for PACE organization operations as a whole, CMS only formalized a requirement to respond appropriately to compliance issues that are identified within the organization, not the proposed requirement to establish a program of auditing and oversight to identify compliance concerns. CMS cited concerns that the burdens associated with implementing compliance oversight would be too great and identified a need for further analysis of such burdens before a requirement could be formalized.

Federal and State Oversight

CMS also reduced the degree of onsite monitoring that will be required of PACE organizations in the future. Under existing rules, new PACE organizations undergo annual onsite reviews during a three-year monitoring period and every two years subsequently. Under the new rules, PACE organizations will be selected for monitoring after the trial period based on a risk assessment, with no mandatory onsite reviews required. This approach would be similar to the approach to monitoring of Medicare Advantage and Part D plans. CMS specifically declined to establish a specific interval for onsite monitoring after the conclusion of the trial period, citing a need for flexibility.

Sanction Authority

CMS updated the regulations to clarify its authority to take enforcement actions other than termination when appropriate, including imposing civil monetary penalties (CMPs). The rule also specifies that CMP amounts would be adjusted annually, consistent with the Federal Civil Penalties Inflation Act Improvement Act of 2015.

Reimbursement Changes

Under current rules, state administering agencies (SAAs), which are the state-level agencies responsible for overseeing PACE organizations, are required to make a monthly capitation payment to PACE organizations for each participant who is a Medicaid beneficiary. The payment amount, which is negotiated by the PACE organization and the SAA, must be specified in the PACE program agreement and must be less than what would otherwise have been paid by the state Medicaid program were the patient not enrolled in PACE, taking into account variables such as the individual's frailty.

However, since the creation of PACE, more states have switched to a managed care model for Medicaid beneficiaries, meaning that Medicaid payments may vary based on various criteria, including beneficiary frailty and other factors. A State Medicaid program's rate-setting process sometimes operates on a different schedule from the PACE contract year. CMS determined that including a specific payment amount in the PACE program agreement has thus become "operationally impossible." In order to create better flexibility, the new rules clarify

that the PACE organization program agreements need not refer to fixed Medicaid capitation rates for a particular contract year. The program agreement may simply describe the methodology that will be used to determine the monthly capitation payment instead of the amount of the fixed monthly payment.

Clarifications

CMS clarified, reorganized, and expanded its authority in several areas affecting PACE organizations, as summarized below.

Medicare Part D Requirements

CMS clarified that, for PACE organizations that offer comprehensive prescription drug coverage (similar to a Medicare Advantage plan that also provides prescription drug coverage), requirements that apply to Medicare Part D plans also apply to PACE organizations, unless the requirement is waived. CMS states that rather than promulgating regulations waiving specific requirements, it would indicate waived requirements on the Part D application for new PACE organizations and the PACE participation agreement and expand upon such waived requirements in subregulatory guidance.

Service Area Expansions, New Locations, and Waivers

The new rules also reorganize and clarify certain requirements related to the application process for organizations seeking to create a new PACE organization, expand the service area of an existing PACE organization, or open a new PACE center. The regulations establish review timelines for expansion applications, applications for new centers and waiver requests, and the timeline for determinations on such requests. CMS will have 45 days from receipt of an expansion or a new center location application to approve, deny, or request additional information from a PACE organization, with two additional 45-day review periods available after the submission of additional information by the PACE organization. If a PACE organization submits an application for both a service area expansion and a new center location, the review period is 90 days. If CMS does not respond to a complete application within the established timeframe, the application is deemed approved, but the 90-day timeframe does not begin until CMS determines that the application is complete. Similarly, for waiver requests (for all application types), CMS has a 90-day response timeframe, but its consideration period does not begin until the application is complete. Finally, if a PACE organization does not respond to a CMS request for additional information within 12 months of a request, the application must be updated.

CHOW Timeframes

CMS will require that organizations submit notification of any proposed change of ownership (CHOW) 60 days in advance, rather than the current 14-day advance notice requirement. Any change defined as a CHOW in 42 C.F.R. § 422.550 (the Medicare Advantage Organization regulations related to CHOWs) would constitute a CHOW for a PACE organization.

Marketing

CMS finalized an approach to marketing materials that largely mirrors its approach to marketing materials for Medicare Advantage Organizations.

Other Changes

CMS formalized multiple additional changes, which are briefly described below:

- Patient Care and Participant Rights. The new rules finalize updates to assessment requirements and schedules, the contents of plans of care, and related requirements. The rules also address processes and procedures for participant enrollment and disenrollment with a PACE organization.

- Record Retention. PACE organizations will be required to retain records for ten years, consistent with the statute of limitations under the False Claims Act.

- Staff Qualifications. PACE organizations may hire individuals with less than one year of experience providing services to the frail elderly if they provide appropriate training to the individuals. The new rules also allow some measure of flexibility to hire individuals with prior criminal convictions (where state law allows) if the PACE organization determines that the individual's history does not pose a risk to participants. Criminal convictions related to abuse or neglect or which are noted elsewhere in federal law (related to program integrity violations) are still disqualifying.