CMS Final Rule Increases Flexibility for PACE Organizations

This article includes a summary analysis from LeadingAge of the new final rule for PACE (Programs of All-Inclusive Care for the Elderly).

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New regulation from CMS increases flexibility for PACE organizations in multiple aspects of program operations. This article provides a summary and analysis of the Final Rule and what it means for PACE organizations.

LeadingAge's Overall Analysis of the Final Rule

The Final Rule includes key provisions that will make it easier for PACE organizations to staff operations. For example, it will allow PACE organizations to hire staff without one year of experience working with elderly/frail populations if those staff are provided training, rather than only being able to draw from those with one year of experience. This will make bringing in potential new talent, particularly at the entry level, easier. It further allows physician assistants and nurse practitioners to serve as the primary care provider, rather than requiring a physician fill this role. It also allows people to fill up to two roles on the interdisciplinary team if they are licensed and qualified to do so.

The Final Rule makes the onsite review process less prescriptive and frequent. For the trial period onsite review, the Final Rule calls for "*observation of program operations.*" This replaces more prescriptive current regulation, which requires chart reviews and interviews, among other items. It removes the requirement for onsite audits every two years after the trial period, reducing burden for both PACE organizations and CMS.

PACE organizations should be aware of new requirements set forth in the Final Rule. For example, they will be required to develop and implement compliance oversight program and to take action if problems arise. There are also changes to requirements related to marketing, including training for contractors, and data/record retention timelines.

There are not many differences between the proposed PACE rule issued in 2016 and the Final Rule. Some key proposals were not finalized, such as requiring PACE organizations to monitor and audit their organizations for compliance. In addition, CMS continues to not apply the HCBS Settings Rule to PACE Organizations.

The Final Rule will take effect in early August. LeadingAge encourages PACE members to review the Final Rule in full, and to be in touch with questions or concerns. LeadingAge will develop resources (e.g., checklists to support our PACE members as they pursue compliance with the Final Rule.

Detailed Summary of the Final Rule

The following is a summary of the Final Rule's key provisions and changes are included below. Technical changes, like minor wordsmithing, are not included. The order of the summary generally follows the order in which items appear in the federal regulation.

Please contact Brendan Flinn (bflinn@leadingage.org) of the LeadingAge staff with questions related to the Final Rule.

Part D Program Requirements

The Final Rule clarifies previous CMS rulemaking with respect to Medicare Part D. Per the Final Rule, PACE organizations that offer prescription drug coverage and meet the definition of being a Part D plan sponsor must follow Medicare Part D program requirements.

Application Requirements

The Final Rule provides clarity to how PACE organizations should go about submitting an expansion application to CMS through their state. Previous rulemaking did not specifically spell this out, but it appears the Final Rule follows existing practice.

Under the Final Rule, the following is required of expansion applications:

- PACE organization must submit an application to CMS to expand its service area and/or to add a new PACE center site. The application may be submitted electronically.
- Applications must include assurances from the PACE organization's state that the state is willing to amend the current PACE program agreement to include the new service area and/or new site.
- The PACE organization must have successfully completed its first trial period audit. If the audit required a corrective action plan, the organization must have that implemented before expanding.

For applicants new to PACE, the Final Rule similarly requires that the relevant state must agree to work with the organization, the applicant must designate a service area it wishes to cover, and CMS may remove already covered areas from the applicant's service area. This is not a change from the previous rule.

The Final Rule also stipulates that both CMS and the state can conduct site visits and other types of review as part of its evaluation of new and expansion applications.

CMS Approval Timeline

The Final Rule maintains the currently practiced 90-day time limit for CMS to decide whether to approve applications for new PACE organizations, and 45 days for CMS to decide on expansion applications. The 45-day time limit is in the PACE Manual, but not in current regulation. The Final Rule reinforces that time period.

It also maintains the 90-day deemed approval provision, which says that if CMS receives all the information it needs and asked for and does not make a decision 90 days after the application's submission, the application is considered approved.

The Final Rule also says that if 12 months pass between the date of an application's initial submission and the applicant's response to a CMS request for additional information, the applicant must update the application in full to reflect the time passed.

How to Submit Applications and Waiver Requests

As is current policy, the Final Rule maintains that all applications to CMS must go through the applicant's state, and the state should review the document and send to CMS.

The current regulation requires that all waiver requests must go through states. The Final Rule adjusts this to allow applicants to submit waiver requests directly to CMS, but that request must include a letter from the state reflecting its view of the request (e.g., concurrence, concerns or conditions).

Waivers will continue to be on a 90-day time period as is current policy. The waiver request must be complete before the time clock begins, and CMS will inform the applicant when their request is considered complete.

Medicaid Rate Methodology

Under current policy, PACE program agreements must include the relevant state's Medicaid capitation rate. The Final Rule amends this to require either the Medicaid capitation rate or the Medicaid rate payment methodology.

This is an optional change for PACE organizations and states and allows new flexibility in the PACE program agreement with respect to Medicaid rate settings. in the Final Rule's narrative, CMS cites examples where including a methodology would be more beneficial than a specific rate, such as instances where states update their PACE Medicaid rates based on a fiscal year schedule that doesn't line up with the timeline of a PACE program agreement. This shift could limit the need to revise the PACE program agreement to reflect specific rate changes.

CMS Sanctions and Civil Monetary Penalties

CMS maintains its current policy on sanctions in the Final Rule and adds a new provision allowing CMS to impose sanctions (including civil monetary penalties and suspension of enrollment) on PACE organizations even if CMS determines itself to have the authority to terminate a PACE program agreement.

This addition allows CMS greater flexibility in how it handles violations of PACE program agreements and may allow more PACE organizations to correct violations without having their agreement terminated. It also reflects the process CMS uses with Medicare Advantage plans, wherein CMS can similarly impose sanctions even if it is authorized to terminate a plan.

In addition, CMS revised the limits on civil monetary penalties to increase what is written into the regulation by inflation. CMS will publish updates to civil monetary penalty limits annually.

Notifying CMS of Organizational Changes

The Final Rule maintains the requirement that PACE organizations planning a change in organizational structure must notify CMS at least 14 days before that change is effective. It adds a new requirement wherein if a PACE organization plans a change of organizational ownership, it must notify CMS and their state sixty (60) days before the change in ownership.

Compliance Oversight Requirements

The Final Rule adds a new requirement for PACE organizations to develop and implement a compliance oversight program, which "must include measures that prevent, detect and correct non-compliance" with PACE program requirements and waste, fraud and abuse.

The program must include a system for promptly responding to, investigating and correcting issues as they are raised.

PACE organizations must conduct a "timely, reasonable inquiry" if they discover "evidence of misconduct related to payment or delivery of items or services." CMS does not define timely or reasonable. They must also conduct "appropriate corrective actions," which could include repaying overpayments and employee disciplinary action and have a system in place to self-report protentional issues to CMS and their state.

Noteworthy here is that CMS did not adopt a proposal to require PACE organizations to monitor and audit their organizations for compliance, as Medicare Advantage and Part D plans are required to do.

Personnel Requirements

The Final Rule loosens current requirements that may have the effect of allowing more entry-level staff to work for PACE organizations. Currently, the regulation requires all employees and contractors to have 1 year of experience with a frail or elderly population, and to meet a standardized set of competencies for their position established by the PACE organization and approved by CMS.

The Final Rule allows individuals who otherwise meet the general requirements (e.g., acting within scope of practice, be legally authorized/licensed to practice) but do not have 1 year of experience with a frail or elderly population to receive "appropriate training from the PACE organization" on working with this population. It also removes the requirement that CMS approve the set of competencies for a specific position.

Employing Persons with Criminal Convictions

The Final Rule adjusts how PACE organizations can employ people with criminal convictions.

PACE organizations will now have discretion to determine whether an individual's contact would pose a potential risk to participants due to a criminal conviction of "physical, sexual, drug, or alcohol abuse." Under current regulation, PACE organizations are not allowed to employ these individuals in any capacity where there might be a risk to participants.

In addition, the Final Rule adds types of people PACE organizations cannot employ, which includes those found guilty of or have a finding in their state's nurse aide registry related to abuse, neglect or mistreatment, as well as those with certain fraud convictions.

Contracted Services

The Final Rule does not significantly broaden the ability to contract services out. It does provide clarity that certain contract requirements apply only to program/medical directors and interdisciplinary team members, such as participating in team meetings.

Immunizations

The Final Rule clarifies a provision in current regulation and requires that all staff providing direct services be "medically cleared for communicable diseases" and have their immunizations up-to-date.

Marketing

The Final Rule clarifies CMS's intent in requiring that marketing materials be published in "other principal languages of the community," as is currently written in regulation.

Under the Final Rule, the state determines any principal languages other than English. In the absence of a state standard, PACE organizations should include languages spoken in the home by at least 5% of individuals living in the service area. These data are available via the U.S. Census Bureau, and this clarification mirrors current requirements in Medicare Advantage.

The Final Rule also clarifies other aspects of marketing requirements. For gifts, PACE organizations can give prospective participants gifts of nominal value ($15 or less) provided they are not cash/adjacent (e.g., gift cards) and are given to people regardless of whether they enroll in PACE.

It also says that any individuals or entities that conduct marketing for a PACE organization where compensation is based on "activities or outcomes" must be trained on PACE program requirements including (specifically) participant rights and participant enrollment and disenrollment. PACE organizations that use contractors for this function must document that this training took place and are responsible for activities marketing contractors conduct on their behalf.

Unsolicited contact, whether it be door-to-door, cold calls and cold emails are not allowed per the Final Rule.

Interdisciplinary Team

The Final Rule makes some significant changes to Interdisciplinary Team requirements that may make it easier for PACE organizations to staff their organizations.

First, it newly allows people to fill two roles on an Interdisciplinary Team provided they are qualified and licensed to fill both.

Second, it broadens the role of "primary care physician" to "primary care provider" and allows a nurse practitioner and/or a physician's assistant to fill this role. In other words, a physician is not required to be part of the Interdisciplinary Team.

The Final Rule also stipulates that all members of the Interdisciplinary Team have needed licenses and certifications under state law and follow state scope of practice laws.

Participant Assessment and Plans of Care

The Final Rule updates requirements for participant assessments.

First, the initial comprehensive assessment must be completed to allow for the development of a plan of care within 30 days from the date of enrollment. The current regulation current does not have a time period in place for the plan of care. If the Interdisciplinary Team determines that

certain services are not necessary, then must document that in the plan of care with a reasoning as to why.

Clinical members from the Interdisciplinary Team must still evaluate the participant in person. A small change in the Final Rule allows other professionals, such as dentists, to also evaluate the person at the Interdisciplinary Team's recommendation, rather than based on a recommendation from an individual on the Interdisciplinary Team.

The assessment criteria in the current regulation are unchanged in the Final Rule.

For the semiannual reassessment, the Final Rule states that the "recreational therapist or activity coordinator" is not required to be present, and that those on the Interdisciplinary Team (the primary care provider, the registered nurse and the social worker) who conduct this assessment are responsible determining who else should on the team should attend the reassessment.

Under current regulation, there must be an annual reassessment that includes a PT, an OT, a dietician and a home care coordinator. Under the Final Rule, this reassessment is no longer required.

Further, the Final Rule allows remote technology to be used for some unscheduled reassessments, in cases where the participant/their representative agrees to it. An in-person reassessment must be conducted if the participant/their representative declines the use of remote technology, and before a PACE organization denies a service request.

New requirements are added in the Final Rule to the plan of care beyond the 30-day time period. Each plan of care must now include not only "identify measurable outcomes to be achieved," but also *"utilize the most appropriate interventions for each of the participant's care needs that advances the participant toward the measurable goals and desired outcomes; identify each intervention and how it will be implemented; identify how each intervention will be evaluated to determine progress in reaching specified goals and desired outcomes."* This is an increase from existing policy.

Participant Rights

The Final Rule clarifies that if a participant opts to disenroll from PACE, they have the right for that disenrollment to be effective the first day of the following month the PACE organization is notified.

It also clarifies that PACE organizations must display participant rights in English and in principal languages of the community, which the Final Rule clarifies to mean languages spoken in the home by at least 5% of individuals living in the service area. These data are available via the U.S. Census Bureau.

Quality Improvement

No notable changes were made to the quality improvement section of the Final Rule, but CMS did change the phrasing from "quality assessment and performance improvement" to "quality improvement".

Eligibility and Enrollment

The Final Rule updated the following provisions related to eligibility and enrollment.

Eligibility Criteria

The Final Rule clarifies that the state criteria is to be used to determine "if an individual's health or safety would be jeopardized by living in a community setting."

Denial of Enrollment

The Final Rule codifies current practice in which PACE Organizations can notify CMS and states of denials of enrollment electronically.

Enrollment Agreement

The Final Rule updates the enrollment agreement to include the following criteria:

"if a Medicaid-only or private pay PACE participant becomes eligible for Medicare after enrollment in PACE, he or she will be disenrolled from PACE if he or she elects to obtain Medicare coverage other than from his or her PO."

Required Items

The Final Rule maintains that a PACE membership card must be given to participants upon enrollment and adds the requirements that the card indicates the person is a participant and includes a PACE organization phone number. The Final Rule removes the need for stickers to be given for the PACE membership card featuring that information.

Disenrollment

The Final Rule updates criteria related to voluntary and involuntary disenrollment.

Voluntary Disenrollment

A person may disenroll from PACE at any time, and the Final Rule specifies that disenrollment will be effective the first day of the following month.

The Final Rule also states that PACE organizations must ensure their employees and contractors do not engage in practices that could reasonably be seen as having the effect of steering or encouraging disenrollment of participants based on changes in health status.

Involuntary Disenrollment

The Final Rule states that if a person is involuntarily disenrolled, that disenrollment takes place the "*first day of the next month that begins 30 days after the day the PACE organization sends notice of the disenrollment to the participant*." For example, notification on June 5 would be effective August 1.

The Final Rule also adds two additional criteria to the current regulation for involuntary disenrollment: 1) if a participant after a 30 day grace period fails to pay or make

arrangements to pay "*any applicable Medicaid spenddown liability or any amount due under the post-eligibility treatment of income process,"* and 2) if a participant's caregiver engages in disruptive or threatening behavior, which the Final Rule defines as "*behavior that jeopardizes the participant's health or safety, or the safety of the caregiver or others."*

Sharing Information with New Providers
The PACE organization per the Final Rule needs to make appropriate referrals and ensure medical records are made available to new providers within 30 days for disenrolled participants.

CMS Monitoring and Corrective Action

The Final Rule removes certain requirements from the trial period onsite review CMS conducts of new PACE organizations. The Final Rule calls for "*observation of program operations.*" This replaces more prescriptive current regulation, which requires chart reviews and interviews, among other items. This change provides CMS more flexibility in its trial period onsite reviews.

The Final Rule also removes the requirement for onsite audits every two years after the trial period. Instead, CMS and states will conduct audits as determined by a risk assessment, which will take into account each organization's performance level and compliance with PACE requirements.

Further, the Final Rule clarifies that corrective action must be taken to address deficiencies identified during ongoing monitoring, reviews and audits, complaints from PACE participants or any other instance identified by CMS or the state.

Record Keeping

The Final Rule requires that PACE organizations maintain records for 10 years from last entry date, an increase from the current regulation's six-year period.

HCBS Settings Rule

The Final Rule reaffirms that the HCBS Settings Rule does not apply to PACE organizations.

In the proposed rule, CMS sought comment related to applying the HCBS Settings Rule to PACE organizations, including to the organizations directly or to their contractors (e.g., if a PACE organization contracted out adult day services, that contractor would have to comply with the HCBS Settings Rule). CMS did not move forward with these pathways in the Final Rule.

For Profit Status

The Final Rule removes the currently written requirement that PACE organizations be not-for profit or government entities. This update reflects changes that were made in 2015 that were not updated in regulation. A summary of that follows.

Historically, PACE organizations have been required to be not-for-profit or government entities, and CMS has had the authority to issue waivers and allow private, for-profit entities to become PACE organizations.

By statute, HHS is required to report to Congress every four years on differences between not-for-profit and for-profit PACE organizations, specifically as it relates to patient frailty, access/quality of care, and costs to Medicare and Medicaid. If there are not determined to be differences between not-for-profit and for-profit PACE organizations, then the requirement for PACE organizations to be not-for-profit or government entities will not apply.

In its most recent report in 2015, HHS did not find significant differences by tax status among the required metrics, thereby nullifying the not-for-profit requirement. This update in the Final Rule reflects this change, that is already in place and required by law.