The Future of PACE Regulation

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Session Objectives

- Review CMS’ proposed changes to current PACE regulation
- Discuss NPA’s comments on proposed changes
- Consider implications of proposed rule for existing PACE organizations and for future expansion and growth of PACE
PACE Regulatory History

- 11/24/1999 – interim final rule published to implement Sections 4801 through 4803 of the Balanced Budget Act of 1997 establishing PACE as permanent provider
- 10/1/2002 – interim final rule published to implement PACE provisions in the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA)
- 12/8/2006 – final rule published to finalize ‘99 and ‘02 interim final rules, establishing current PACE regulatory requirements
- 8/16/2016 -- CMS published proposed rule to update PACE requirements with request for comments
- 10/17/2016 – deadline for submission of comments on proposed rule
- ??/??/201? – CMS to publish final rule after consideration of comments on proposed rule
Key Proposed Changes

- Changes to requirements for PACE organization (PO) staff
- Changes to requirements for Interdisciplinary Team (IDT)
- Changes to IDT assessment and reassessment requirements
- Expanded compliance oversight requirements
- Prohibition on marketing by individuals other than PACE employees
Principles Underlying NPA’s Recommendations

• Provide flexibility in PACE operations that supports efficiency and growth, to enhance value to PACE participants and expand access to the program

• Promote participant-centered services, guided by the needs and preferences of the PACE participant

• Preserve the provider-based attributes of the PACE program that establish its direct care relationship with its participants, address gaps in the availability of care generally and in geriatric-competent care specifically, and enhance the participant’s access to an integrated delivery system
• Proposed Change: Adds new §460.3 to state that PACE organizations (POs) must meet applicable Part D requirements.

• NPA Response:
  • Concur, with request that §460.3 also refer to waivers of Part D requirements for POs when such requirements duplicate or are in conflict with PACE requirements, or are needed to improve coordination of Part D and PACE benefits.
  • NPA asks CMS to specify whether or not Part D guidances are applicable to POs and requests that audits take into account differences between POs, and MA-PDs and PDPs.
  • NPA requests opportunity to work with CMS on ways to reduce Part D premiums for Medicare-only beneficiaries.
Subpart B—PACE Organization Application and Waiver Process

§460.10: Purpose; §460.12: Application requirements; §460.20 Notice determination

• Proposed Changes:
  • Clarify that application processes apply for both entities submitting initial applications and POs seeking to expand their service areas and/or open a new PACE center.
  • Largely codify current application processes in regulation.
  • Requires update to application if more than six months elapse between application submission and applicant’s response to RAI.

• NPA Response:
  • Request for notification, rather than application, process for POs seeking to open new centers in existing service areas.
  • In situations where there is a time lag between submission of application and response to RAI, allow for updates to existing application vs. new application, and allow for 12, not 6, months to elapse before updates are required.
Subpart D—Sanctions, Enforcement Actions, and Termination

§460.40: Violations for which CMS may impose sanctions

• Proposed Change: Gives CMS discretion to impose sanctions or civil money penalties (CMPs) in situations when CMS is authorized to terminate a PO under current requirements, e.g., inability to ensure health and safety of participants, or failure “to comply substantially with conditions for a PACE program…, or with terms of its PACE Program Agreement.”

• NPA Response:
  • Appreciate alternatives to program termination but warn against potential for sanctions and CMPs to equate to termination if excessively high; encourage CMS to utilize discretion.
  • Encourages ongoing efforts to improve consistency of audits across regions.
Subpart E—PACE Administrative Requirements

§460.60: PACE organizational structure

• Proposed Change: Removal of requirement for POs to be not-for-profit entities.

• NPA Response: Recognizes potential for PACE growth; calls upon CMS to ensure that both not-for-profit and for-profit POs are held to uniform standards.

• Proposed Change: Clarifies 60-day notice requirement for PO Change of Ownership (CHOW).

• NPA Response: Requests further clarification of when CHOW requirements apply; requests expedited application process in cases when CHOW involves an acquiring entity that is not a PACE organization.
• Proposed Change: Adds §460.63 imposing new compliance oversight requirements on POs. Compliance oversight program must include the following:

  • System for routine monitoring and identification of compliance risks, including internal monitoring and audits and, as appropriate external audits, to evaluate the PO, including contractors, compliance with CMS requirements and effectiveness of compliance oversight program.
  • System for responding to compliance issues, investigating potential compliance problems, correcting such problems and ensuring ongoing compliance.
  • Measures to prevent, detect and correct fraud, waste and abuse, and procedures to voluntarily self-report potential fraud or misconduct to CMS and State Administering Agency (SAA).
NPA Response to new §460.63:

- NPA considers expanded internal oversight requirements as a tradeoff of sorts for less frequent audits.
- Evaluation of POs’ compliance oversight programs should recognize differences between POs, and Medicare Advantage and Part D plans, in terms of size, structure, resources, etc.
- Anticipate cost of implementing new requirement will be considerably higher than CMS estimates of approximately $12,000 annually.
- Request minimum 12 month period after publication of final rule to comply with new requirement.
Proposed Change: Eliminate current “one-year prior experience” requirement allowing POs to hire staff who do not have one year of experience with a frail or elderly population by providing them with necessary training.

NPA Response: Concur with proposed change.
CMS Request for Comment: For future rulemaking, CMS seeks comments on whether it should apply Home and Community Based Settings (HCBS) requirements to PACE organizations.

NPA Response: Oppose applying HCBS rule to PACE for two reasons: (1) consistency between HCBS and PACE rules makes imposition of HCBS rule largely duplicative; and (2) strict application of HCBS rule may impact ability of POs to provide care to PACE participants in ways that have been demonstrated successful at delaying or preventing nursing home placement.
• Proposed Change: Prohibits POs from using any individuals other than employees of the PACE organization for marketing.

• NPA Response:
  • Oppose change, recommend retaining current requirement that prohibits POs from “contracting outreach efforts to individuals or organizations whose sole responsibility involves direct contact with the elderly to solicit enrollment.”
  • Comment distinguishes between marketing and enrollment activities, and POs and MA/Part D plans.
Proposed Change: CMS proposes a definition of a “principal language of the community” in states where no such standard exists. The proposed standard is a language that is spoken in the home by at least 5% of the individuals in the PO’s service area. Would require marketing materials to be printed and participant rights to be written and displayed in these languages.

NPA Response:

- Define the principal languages based on languages spoken in the home by PACE-eligible individuals, e.g., by those 55 years of age and older in the PO’s service area.
- Increase percentage from 5% to 10%.
Subpart F—PACE Services

§460.98: Service delivery

• CMS Request for Comment: For future rulemaking, CMS requests input on ways to allow greater flexibility with regard to settings in which IDT members provide PACE services.

• NPA Response:
  • Advocate for greater flexibility in terms of PACE participants’ use of the PACE Center.
  • Advocate for greater flexibility in use of Alternative Care Settings.
  • Advocate for greater flexibility in terms of the relationship between the IDT and the PACE Center.
Subpart F—PACE Services

§460.98: Service delivery

• NPA Principles on settings of care:
  • All PACE participants must be assigned to a PACE IDT, but the IDT does not have to be assigned to a PACE center.
  • All POs must have at least one PACE center.
  • All PACE participants must have access to a PACE center (with possible allowances for rural POs), but assignment to a PACE center should not be required.
  • PACE participants may receive services in settings other than the PACE center, home and inpatient facilities, consistent with their individualized care plans.
  • Assessing whether a PO has sufficient PACE center capacity should take into account the availability and participants’ use of ACSs.
Proposed Change: CMS proposes expanded definition of primary care provider (PCP) on IDT to include: nurse practitioners, physician assistants, community-based physicians.

NPA Response: Concur, with following additional comments:

- Allow for community-based NPs and PAs as is the case with physicians.
- Allow for some flexibility in how community-based PCPs participate in PACE IDT discussions, e.g., directly or through use of primary care liaison.
Subpart F—PACE Services

§460.102: Interdisciplinary team

• Proposed Change: Allow for an IDT members to fulfill a maximum of two separate roles on the IDT.

• NPA Response: Concur.

• Proposed Change: Eliminate “primarily serve” requirement for community-based physicians.

• NPA Response: Advocate for “primarily serve” requirement to be eliminated for all IDT members.
CMS Request for Comment: CMS requests input on possibility of deleting requirements in §460.102(b) related to composition of the PACE IDT.

NPA Response: NPA advocates for retaining the range of health professionals and functions identified in §460.102(b) that a PO must be able to convene: PCP, RN, MSW, PT, OT, RT/activity coordinator, PACE center manager, dietitian, home care coordinator, driver/representative, personal care aide/representative, but recommends IDT members required for distinct types of assessments and care plans reflect the scope and intent of each type. NPA’s approach calls for composition of the IDT to vary over time and in response to the needs of individual participants.
Subpart F—PACE Services

§460.104: Participant assessment

<table>
<thead>
<tr>
<th>Assessment</th>
<th>IDT members required currently</th>
<th>IDT members required under proposed rule</th>
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<tbody>
<tr>
<td>Initial comprehensive assessment</td>
<td>MD, RN, MSW, PT, OT, RT/activity coordinator, dietitian, home care coordinator, other professionals at recommendation of individual IDT members</td>
<td>PCP, RN, MSW, PT, OT, RT/activity coordinator, dietitian, home care coordinator, other professionals at recommendation of the IDT</td>
</tr>
<tr>
<td>Semiannual reassessment</td>
<td>MD, RN, MSW, RT/activity coordinator, other team members actively involved in the development or implementation of the participant’s plan of care, e.g., home care coordinator, PT, OT, dietitian</td>
<td>PCP, RN, MSW, other team members that the PCP, RN and MSW determine are actively involved in the development or implementation of the participant’s plan of care</td>
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<tr>
<td>Annual reassessment</td>
<td>MD, RN, MSW, RT/activity coordinator, PT, OT, dietitian, home care coordinator</td>
<td>PCP, RN, MSW, other team members that the PCP, RN and MSW determine are actively involved in the development or implementation of the participant’s plan of care</td>
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# Subpart F—PACE Services

## §460.104: Participant assessment

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<td>Unscheduled due to change in health status</td>
<td>MD, RN, MSW, PT, OT, RT/activity coordinator, dietitian, home care coordinator</td>
<td>PCP, RN, MSW, other team members that the PCP, RN and MSW determine are actively involved in the development or implementation of the participant’s plan of care</td>
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<tr>
<td>Unscheduled due to participant/designated representative request to initiate, eliminate, or continue a particular service</td>
<td>Appropriate members of the IDT, as identified by the IDT</td>
<td>PCP, RN, MSW, other team members that the PCP, RN and MSW determine are actively involved in the development or implementation of the participant’s plan of care</td>
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### Subpart F—PACE Services

#### §460.104: Participant assessment; §460.106: Plan of care

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<th>NPA Recommended Care Planning Team</th>
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<tr>
<td>Initial/Upon Enrollment</td>
<td>Core Assessment Team (CAT) made up of PCP, RN, MSW plus: PT, OT, RT/activity, dietitian, home care coordinator; CAT may add other professionals as needed</td>
<td>CAT plus: PT, OT, RT/activity, dietitian, home care coordinator; CAT may add other professionals as needed</td>
</tr>
<tr>
<td>Semiannual</td>
<td>CAT; CAT may add assessments by other IDT members as needed</td>
<td>CAT plus: other IDT members who performed a semiannual reassessment and other IDT members who the CAT determines are actively/substantively involved in participant’s care</td>
</tr>
<tr>
<td>Annual</td>
<td>CAT plus: PT or OT; CAT may add assessments by other IDT members as needed</td>
<td>CAT plus: PT or OT; other IDT members who performed an assessment; and other IDT members who the CAT determines are actively/substantively involved in participant’s care</td>
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<td>Unscheduled due to service request</td>
<td>CAT determines which IDT members are related to service request; related IDT members conduct the assessment(s) as needed</td>
<td>CAT plus: members of the IDT who conducted an assessment; and other IDT members who the CAT determines are actively and substantively involved in participant’s care</td>
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Proposed Change: Requires initial assessment to be completed in time to allow IDT to complete the plan of care within 30 days of enrollment.

NPA Response: Concur, with allowance, in extenuating circumstances, for PO to document reasons that care plan was not completed within 30 days without being determined to be out of compliance.
Proposed Change: Requires assessments to be consolidated into a plan of care (POC) through “team discussions” rather than “discussions in team meetings” allowing for in-person meeting, conference call, or video conferencing.

NPA Response: Concur.

Proposed Change: Requires IDT to document in POC the reasons services “associated with the comprehensive assessment criteria” are not included in the POC.

NPA Response: Oppose change; argue that POC should focus on services provided and that participant has right to file an appeal for a service that is not included in POC.
Subpart I—PACE Enrollment & Disenrollment

§460.162: Voluntary disenrollment

- Proposed Change: Requires voluntary disenrollments to be effective on the first day of month following the date the PO receives participant’s notice of voluntary disenrollment.

- NPA Response: Favor current requirements to 1) use most expedient process allowed under Medicare and Medicaid; and 2) coordinate disenrollment date between Medicare and Medicaid for dual-eligible participants.

- Proposed Change: Requires that POs ensure employees or contractors do not engage in any practice that would reasonably be expected to have the effect of steering or encouraging disenrollment of PACE participants due to change in health status.

- NPA Response: Concur, with understanding that POs should not be held responsible for a participant’s independent decision to disenroll.
Proposed Change: Requires involuntary disenrollments to be effective on the first day of the next month that begins 30 days after the day the PACE organization sends notice of disenrollment to the participant.

NPA Response: Concur that participants should receive adequate advance notice of involuntary disenrollment, but advises that a disenrollment resulting from a participant being out of the PO’s service area for more than 30 days should take effect as quickly as possible.
• Proposed Change: CMS proposes to add requirement that Medicaid payment, “is sufficient and consistent with efficiency, economy and quality of care.”

• CMS Request for Comment: CMS seeks comments on other rate methodologies that CMS may consider requiring for Medicaid capitation amounts for PACE.

• NPA Response: Concur, with recommendation that CMS require Medicaid capitation payments take into account that POs are responsible and at full financial risk for all Medicaid-covered services, including long-term nursing home care without any restrictions or rate adjustments for length of stay. NPA also recommends that Medicaid rate-setting approaches recognize distinct cost experiences of different subpopulations, e.g., dual-eligible vs. Medicaid only beneficiaries, beneficiaries with Part A or Part B only, different age cohorts, beneficiaries with significant behavioral health diagnoses, etc.
DISCUSSION