The PACE Final Rule: Impact on Regulatory Requirements for PACE

June 11, 2019

Session Objectives

- Understand changes to PACE regulatory requirements as a result of PACE final rule
- Revisit key PACE requirements
- Identify action items for PACE organizations/prospective PACE organizations in response to PACE final rule

Sources of CMS Information

- Current PACE rule: https://www.ecfr.gov/cgi-bin/text-idx?SID=be7f10fcebe1e72e583e57893de0655c&mc=true&node=pt42.4.460&rgn=div5
- PACE final rule as published in Federal Register, June 3rd, 2019: https://www.govinfo.gov/content/pkg/FR-2019-06-03/pdf/2019-11087.pdf
- CMS Fact Sheet: https://www.cms.gov/newsroom/fact-sheets/programs-all-inclusive-care-elderly-pace-final-rule-cms-4168-f
- CMS Press Release: https://www.cms.gov/newsroom/press-releases/cms-modernizes-care-frail-elderly-individuals-enrolled-pace

NPA Regulatory Resources

- Link to https://www.npaonline.org/policy-and-advocacy/federal-regulatory-policy* for:
  - NPA High-level summary of PACE Final Rule, *May 29, 2019*
  - NPA Detailed summary of PACE Final Rule, *June 5, 2019*
  - NPA "Red-lined" version of PACE rule incorporating revisions in June 3rd PACE Final Rule (Appendix A)
  - NPA PowerPoint presentation on PACE Final Rule, *June 11, 2019*

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* Must be logged in as NPA member to access information on NPA website

Effective Date

- The final rule published on June 3, 2019 is effective August 2, 2019
- POs must closely review the final rule, including both regulatory and preamble language, and make necessary changes to achieve compliance with new and revised requirements by August 2, 2019.
- Current regulations in effect until August 2, 2019
  - e.g., cannot utilize NPs in primary care provider role on IDT until August 2, 2019 in absence of approved BIPA 903 waiver
  - e.g., cannot have one individual on IDT fulfill two roles on IDT until August 2, 2019
  - And so on

Big Picture Changes

- Operational/regulatory flexibility
- Codification of current policies
- Removal of outdated information
- Administrative flexibility for CMS

§460.3 Part D Program Requirements (new)

§460.3 Part D Program Requirements

PACE organizations offering qualified prescription drug coverage and meeting the definition of a Part D plan sponsor, as defined in §423.4 of this chapter, must abide by all applicable Part D program requirements in part 423 of this chapter.

- Final Rule codifies current policy.
- No specific action required of PACE organizations (POs).

§460.10 Purpose (revised)

§460.10 Purpose

(a) Applications. This subpart sets forth the application procedures for the following:

(1) An entity that seeks approval from CMS as a PACE organization.

(2) A PACE organization that seeks to expand its service area or to add a new PACE center.

(3) A PACE organization that seeks to expand its service area and to add a new PACE center.

(b) Waiver. This subpart sets forth the process by which a PACE organization may request waiver of certain regulatory requirements. The purpose of the waivers is to provide for reasonable flexibility in adapting the PACE model to the needs of particular organizations (such as those in rural areas).

- Change made to clarify that, in addition to applications submitted by entities seeking to become POs, POs may submit applications to expand service area and/or add new PACE center.
- Final Rule codifies current policy (see PACE manual, Chapter 17, Sec. 20.4 (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pace111c17.pdf) and PACE application (https://www.cms.gov/Medicare/Health-Plans/PACE/Downloads/PACE_Initial_and_Service_Area_Expansion_Application_2019.pdf))
- No specific action required of POs/applicants other than adherence to application requirements.

§460.12 Application requirements (revised)

§460.12 Application requirements

(a) Submission of application. An individual authorized to act for an entity that seeks to become a PACE organization or a PACE organization that seeks to expand its service area and/or add a PACE center site must submit to CMS a complete application in the form and manner specified by CMS that describes how the entity or PACE organization must meet all requirements in this part.

- Again, clarifies that, in addition to applications submitted by entities seeking to become POs, POs may submit applications to expand service areas and/or add new PACE centers.
- Clarifies that applications must be submitted in the "form and manner specified by CMS," allowing for formats other than paper.
- Deletes language that spoke to "priority consideration" and "special consideration" in processing of applications; such considerations are no longer relevant.
- Codification of current policy; no specific action required of POs/applicants other than adherence to application requirements.

§460.12 Application requirements, cont.

§460.12(b) State assurance. (1) An entity's application to become a PACE organization must include an assurance from the State administering agency of the State in which the program is located indicating that the State considers the entity to be qualified to be a PACE organization and is willing to enter into a PACE program agreement with the entity.

(2) A PACE organization's application to expand its service area and/or add a PACE center site must include an assurance from the State administering agency of the State in which the program is located indicating that the State is willing to amend the PACE program agreement to include the new site and/or expand the PACE organization's service area.

- Clarifies that all applications including those from POs to expand service areas and/or add PACE centers must include an assurance from the State administering agency (SAA).
- Codification of current policy; no specific action required of POs/applicants other than adherence to application requirements.

§460.12 Application requirements, cont.

§460.12(c) Service area designation. (1) An entity submitting an application to become a PACE organization or a PACE organization submitting an application seeking to expand its service area must describe the proposed service area in its application.

(2) CMS, in consultation with the State administering agency, may exclude from designation an area that is already covered under another PACE program agreement to avoid unnecessary duplication of services and avoid impairing the financial and service viability of an existing program.

- Moves language from §460.22 (now deleted) into §460.12(c) regarding service area designation and ability for CMS, in consultation with SAA, to exclude from service area an area already covered under another PACE program agreement.
- Clarifies that initial and service area expansion applications must include a description of the proposed service area.
- Codification of current policy; no specific action required of POs/applicants other than adherence to application requirements.

§460.12 Application requirements, cont.

§460.12(d) Service area and/or PACE center site expansion. CMS and the State administering agency will only approve a service area expansion or PACE center site expansion after the PACE organization as successfully completed its first trial period audit and, if applicable, has implemented an acceptable corrective action plan.

- Stipulates that service area and/or PACE center site expansion only possible after the PO's completion of first trial period audit and, if applicable, implementation of acceptable CAP.
- Codification of current policy (see PACE manual, Chpt. 17, Sec. 20.4); no specific action required of POs other than adherence to application requirements.
- Preamble further stipulates that relocation of PACE center due to emergency or unforeseen circumstances is possible prior to completion of first trial period audit; however, relocation of a PACE center during this period to assure adequate access if program growth exceeds enrollment projections must await completion of first trial period audit.

§460.18 CMS evaluation of applications (revised)

§460.18 CMS evaluation of applications.

CMS evaluates an application on the basis of the following information:

(a) Information contained in the application.

(b) Information obtained by CMS or the State administering agency through on-site visits or any other means.

- Clarifies that CMS' evaluation of applications includes initial applications as well as service area and/or PACE center site expansion applications.
- Clarifies that in its evaluation of applications CMS may use information obtained by CMS or the SAA through on-site visits as well as by other means, e.g., information obtained from financial reviews or ongoing monitoring visits.
- Codification of current policy; no specific action required of POs/applicants other than adherence to application requirements.

§460.20 Notice of CMS determination (revised)

§460.20 Notice of CMS determination.

(a) Time limit for notification of determination. Within 90 days, or 45 days for applications set forth in §460.10(a)(2), after an entity submits a complete application to CMS, CMS takes one of the following actions in the form and manner specified by CMS:

(1) Approves the application.

(2) Denies the application and notifies the entity in writing of the basis for the denial and the process for requesting reconsideration of the denial.

- Recognizes timeframes for both initial applications as well as applications for service area and/or PACE center site expansions.
- Codification of current policy; no specific action required of POs/applicants other than adherence to application requirements.

§460.20 Notice of CMS determination, cont.

§460.20(b) Complete application. An application is only considered complete when CMS receives all information necessary to make a determination regarding approval or denial.

(c) Additional information requested. If CMS determines that an application is not complete because it does not include sufficient information to make a determination, CMS will request additional information within 90 days, or 45 days for applications set forth in §460.10(a)(2), after the date of submission of the application.

(1) The time limits in paragraph (a) of this section do not begin until CMS receives all requested information and the application is complete.

(2) If more than 12 months elapse between the date of initial submission of the application and the entity's response to the CMS request for additional information, the entity must update the application to provide the most current information and materials related to the application.

- Recognizes Request for Additional Information (RAI) timeframes for both initial applications as well as applications for service area and/or PACE center site expansions. This is codification of current policy.
- §460.120(c)(2) stipulates that applications must be updated if more than 12 months elapse between date of submission and entity's response to RAI; doesn't require new application, but this could be necessary if there was a material change to the application.
- Largely codification of current policy; no specific action required of POs/applicants other than adherence to application requirements.

§460.20 Notice of CMS determination, cont.

§460.20(d) Deemed approval. An entity's application to become a PACE organization is deemed approved if CMS fails to act on the complete application within 90 days, after the later of the following dates:

(1) The date the application is submitted by the organization.

(2) The date CMS receives all requested additional information.

(e) Date of submission. For purposes of the time limits described in this section, the date that an application is submitted to CMS is the date on which the application is delivered to the address designated by CMS.

- Note that deemed approval applies to initial applications but not to applications for service area and/or PACE center site expansions.
- Codification of current policy; no specific action required of applicant other than adherence to application requirements.

§460.22 Service area designation (deleted/moved)

- §460.22 is deleted; information moved to §460.12(c).

§460.26 Submission and evaluation of waiver requests (revised)

§460.26 Submission and evaluation of waiver requests.

(a) A PACE organization, or an entity submitting an application to become a PACE organization, must submit its waiver request through the State administering agency for initial review.

(1) The State administering agency forwards a PACE organization's waiver requests to CMS along with any concurrence, concerns or conditions regarding the waiver.

(2) Entities submitting an application to become a PACE organization may:

(i) Submit a waiver request as a document separate from the application by submitting it first to the State administering agency which, in turn, will forward the waiver request to CMS indicating the State's concurrence, concerns or conditions regarding the waiver request; or

(ii) Submit a waiver request directly to CMS in conjunction with the application. This request must include a letter from the State administering agency indicating the State's concurrence, concerns or conditions regarding the waiver request.

- Clarifies waiver request process; provides for waiver requests to be submitted independently or in conjunction with an application.
- Note that the waiver request must always be submitted to the SAA for initial review. Subsequently, the waiver request can be submitted to CMS by the SAA or, in situations involving applications, it may also be included in the application with a letter from the SAA indicating its concurrence, concerns or conditions.
- Codification of current policy; no specific action required of POs/applicants other than adherence to waiver request requirements.

§460.26 Submission and evaluation of waiver requests (revised)

§460.26(b) CMS evaluates a waiver request from a PACE organization or PACE applicant on the basis on the basis of the following information: …

- The only change to this section is to clarify that a waiver request may be submitted by a PACE applicant as well as a PO. No changes to the information CMS uses to evaluate a waiver request, etc..
- Codification of current policy; no specific action required of POs/applicants other than adherence to waiver request requirements.

§460.28 Notice of CMS determination on waiver requests (revised)

§460.28(a) General. Within 90 days after receipt of a complete waiver request, CMS takes one of the following actions, in the form and manner specified by CMS:

(1) Approves the waiver request.

(2) Conditionally approves the waiver request and notifies the PACE applicant.

(3) Denies the waiver request and notifies the PACE organization or PACE applicant of the basis for the denial.

- CMS clarifies that notice of CMS' determination is within 90 days of receipt of complete waiver request.
- Explains that a conditional approval applies in situations when the waiver request is submitted in conjunction with an initial application, i.e., waiver approval is conditional on approval of the application.
- CMS reserves ability to specify the form and manner in which notice of its determination will be provided.
- No specific action is required of POs/applicants other than adherence to waiver request requirements.

§460.28 Notice of CMS determination on waiver requests, cont.

§460.28(b) Additional information requested. A waiver request is only considered complete when CMS receives all information necessary to make a determination regarding approval or denial. If CMS determines that the waiver request is not complete because it does not include sufficient information to make a determination, CMS will request additional information from the PACE organization or PACE applicant. The 90-day time limit in paragraph (a) of this section will start when CMS receives the complete waiver request.

- Further explanation of what constitutes a complete waiver request and that CMS' 90-day review period commences with receipt of complete request.
- In contrast to the application process, there is no specific process or timeframe associated with requesting additional information in the context of a waiver request.
- No specific action is required of POs/applicants other than adherence to waiver request requirements.

§460.28 Notice of CMS determination on waiver requests, cont.

§460.28(c) Waiver approval. A waiver request is deemed approved if CMS fails to act on the request within 90 days after CMS receives a complete waiver request.

(d) Withdrawal of CMS approval for good cause.

(1) CMS in consultation with the State administering agency may withdraw approval of a waiver for good cause.

(2) If the waiver approval is withdrawn, CMS must notify the PACE organization or PACE applicant and the State administering agency that approval of a waiver has been withdrawn and the reason for doing so and must specify the effective date of the withdrawal in the notice.

- Indicates that a waiver request is deemed approved if CMS takes no action on the request within 90 days of receipt of a complete waiver request.
- Regulatory language provides more detail related to withdrawal of CMS approval of a waiver for good cause.
- Codification of current policy; no specific action is required of POs/applicants other than adherence to waiver request requirements.

§460.32 Content and terms of PACE program agreement (revised)

§460.32(a)(12) The state's Medicaid capitation rate or Medicaid payment rate methodology, and the methodology used to calculate the Medicare capitation rate.

- Rather than requiring that the program agreement include the Medicaid capitation rate(s), the regulation now allows for the program agreement to include either the rate(s) or a description of the Medicaid payment rate methodology.
- This change is intended to address challenges with including specific rates in states moving toward rate-setting methodologies that result in numerous payment variations, perhaps even individual risk-adjusted rates.
- This change may also reduce administrative challenges/burden associated with annual updates to program agreements.
- No specific action is required of POs.
- Note a consistent change is made to *§460.182(b) Medicaid payment*.

§460.40 Violations for which CMS may impose sanctions (revised)

Lettering/numbering throughout this section revised with addition of new:

§460.40(b) If CMS or the State administering agency makes a determination that could lead to termination of a PACE program agreement under §460.50, CMS may impose any of the sanctions specified at §§460.42 and 460.46.

- While this change expands the circumstances that could lead to a sanction, it also provides CMS an alternative to program termination in these situations. Broadly, §460.50 allows for termination for cause in the following circumstances: (b) Termination due to uncorrected deficiencies; and (c) Termination due to health and safety risk.
- No specific action is required of POs.

§460.46 Civil money penalties (revised)

§460.46(a) CMS may impose civil money penalties up to the maximum amounts specified in paragraphs (a)(1) through (4) of this section. These amounts will be adjusted in accordance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701) of Pub.L. 114-74) and updated amounts specified in 45 CFR part 102.

- The most significant change in this section is to clarify that civil money penalty (CMP) amounts will be adjusted for inflation.
- Codification of current policy; no specific action required of POs.
- Note: Current CMP amount adjusted for inflation is $38,159.

§460.60 PACE organizational structure (revised)

Language in §460.60 prohibiting POs from operating as for-profits outside demonstration status was eliminated.

Lettering throughout this section revised with addition of new:

§460.60(d) Change of ownership. A PACE organization planning a change of ownership must comply with all requirements in 42 CFR part 422, subpart L, and must notify CMS and the State administering agency, in writing, at least 60 days before the anticipated effective date of this change.

- In the preamble to the final rule, CMS reiterates its existing requirement for an acquiring entity in a change of ownership (CHOW) situation to be qualified as a PO if it is not already. Hence, if an acquiring entity is not already qualified as a PO, it must complete CMS' PACE application process as well as state-specific application processes.
- Codification of current policy; no specific action required of POs unless they pursue a change in organizational structure or CHOW.
- Note: for changes in organizational structure other than a CHOW that affect the philosophy, mission and operations of the PO, the PO must notify CMS and the SAA, in writing, at least 14 days before the change takes place.

§460.62 Governing body (revised)

§460.62(a) Governing body. A PACE organization must be operating under the control of an identifiable governing body (for example, a board of directors) or a designated person functioning as a governing body with full legal authority and responsibility for the following:

…

(7) A quality improvement program as described in §460.130.

- Clarifies the responsibilities of the governing body with respect to its responsibility for the PO's quality improvement program as defined in §460.130.
- If necessary, PO may want to more specifically document the roles and responsibilities of its governing body consistent with the change to §460.62(a)(7).

§460.63 Compliance oversight requirements (new)

§460.63 Compliance oversight requirements

A PACE organization must adopt and implement effective compliance oversight requirements, which must include measures that prevent, detect, and correct non-compliance with CMS' 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.

(a) If the PACE organizations discovers evidence of misconduct related to payment or delivery of items of services, it must conduct a timely, reasonable inquiry into that conduct.

(b) The PACE organization must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees) in response to the potential violation.

(c) The PACE organization should have procedures to voluntarily self-report potential fraud or misconduct related to the PACE program to CMS and the State administering agency.

- The addition of §460.63 to 42 CFR part 460 imposes specific compliance oversight requirements for POs and their compliance oversight program.
- POs must ensure their compliance oversight program includes procedures for self-monitoring compliance with CMS requirements as well as measures to prevent, detect and correct fraud, waste and abuse. Additionally, POs must have procedures to respond promptly to compliance/FWA issues identified in the course of their self-monitoring activities.

§460.64 Personnel qualifications for staff with direct participant contact (revised)

§460.64(a) General qualification requirements. Each member of the PACE organization's staff (employee or contractor) that has direct contact with participants must meet the following conditions:

…

(3) Have 1 year of experience working with a frail or elderly population or, if the individual has less than 1 year of experience but meets all other requirements under paragraph (a) of this section, must receive appropriate training from the PACE organization on working with a frail or elderly population upon hiring.

- Allows for more flexibility in hiring of staff that has direct contact with participants.
- Required training must be based on industry standards and may be provided directly by the PO or through a training entity.
- POs may need to modify materials related to recruitment of impacted staff. If POs choose to hire staff that do not meet the one-year prior experience requirement, they will need to confirm that trainings and related materials are based on industry standards and provide individuals with necessary information/skills. POs also must document compliance with 1 year prior experience requirement or receipt of training for direct care staff.
- Also, a modification to 460.64(a)(4) no longer requires that standardized competencies have to be approved by CMS.

§460.68 Program integrity (revised)

§460.68(a) Persons with criminal convictions. A PACE organization must not employ individuals or contract with organizations or individuals–

…

(3) 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;

(4) 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

(5) Who have been convicted of specific crimes for any offense described in section 1128(a) of the Social Security Act

- §460.68(a)(3) has been revised to provide the PO more discretion to determine if the individual's contact with participants poses a risk.
- §§460.68(a)(4) and (5) are new.
- CMS notes these changes make PACE requirements more consistent with those applicable in long term care facilities.
- POs may need to modify policies and procedures referencing requirements of employees and contractors and revise their employment applications consistent with these changes. In addition, POs should confirm that any vendors they work with who perform background checks, etc. are aware of these changes and implement any needed changes to their processes.

§460.70 Contracted Services (revised)

§460.70(d) Content of contract. Each contract must be in writing and include the following information:

…

(6) With respect to an individual who is contracting as a program director or medical director or to be part of the interdisciplinary team as set forth at §460.60(a) and (b) and §460.102(b), the contract must specify that the individual agrees to:

(i) Perform all the duties related to its position as specified in this part.

(ii) Participate in interdisciplinary team meetings as required.

(iii) Be accountable to the PACE organization.

(iv) Cooperate with the competency evaluation program and direct participant care requirements specified in §460.71

- More clearly stipulates specific contractual requirements for the PACE program director, medical director and IDT members; the intent of this change is to enhance clarity and is consistent with how the regulation has been interpreted.
- If necessary, PO may want to clarify policies and procedures referencing requirements of individuals in these roles and revise contractual agreements applicable to these positions.

§460.71 Oversight of direct participant care (revised)

§460.71(b) The PACE organization must develop a program to ensure that all staff furnishing direct participant care services meet the following requirements:

…

(4) Be medically cleared for communicable diseases and have all immunizations up-to-date before engaging in direct participant contact as required under §460.64(a)(5).

…

(c) The PACE organization must develop a training program for each personal care attendant to establish the individual's competency in furnishing personal care services and specialized skills associated with specific care needs of individual participants.

(d) Personal care attendants must exhibit competency before performing personal care services independently.

- Language in §460.71(b)(4) was modified to make it consistent with §460.64(a)(5).
- §§460.71(c) and (d) were formerly §§460.66(b) and (c) and moved to §460.71 to consolidate requirements regarding training of staff and competency evaluations for employees and contracted staff furnishing care directly to participants.

§460.82 Marketing (revised)

§460.82(c) Special language requirements. A PACE organization must furnish printed marketing materials to prospective and current participants as specified below:

(1) In English and in any other principal languages of the community, as determined by the State in which the PACE organization is located. In the absence of a State standard, a principal language of the community is any language that is spoken in the home by at least 5 percent of the individuals in the PACE organization's service area.

- POs which have no state standards for principal languages must determine which principal languages apply in their service areas and be able to furnish printed marketing materials in these languages consistent with this change. POs should consult with their CMS account managers for information on these languages. This requirement is consistent with Medicare Advantage requirements.

§460.82 Marketing, cont.

§460.82(e) Prohibited marketing practices. A PACE organization must not use the following marketing practices, which are prohibited:

…

(3) Gifts or payments to induce enrollment, unless the gifts are of nominal value as defined in CMS guidance, are offered to all potential enrollees without regard to whether they enroll in the PACE program, and are not in the form of cash or other monetary rebates.

- In the preamble to the final rule, CMS explains that nominal value is defined consistently for POs, and Medicare Advantage and Part D plans, and instructs POs to look to these two programs for the definition of nominal value – currently $15 – and future updates (Medicare Communications and Marketing Guidelines, Section 40.4; https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/CY2019-Medicare-Communications-and-Marketing-Guidelines_Updated-090518.pdf)
- POs must ensure marketing policies are consistent with regulatory requirements.

§460.82 Marketing, cont.

§460.82(e) Prohibited marketing practices. A PACE organization must not use the following marketing practices, which are prohibited:

…

(4) Marketing by any individual or entity that is 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, including but not limited to, subparts G and I of this part.

(i) PACE organizations are responsible for the activities of contracted individuals or entities who market on their behalf.

(ii) PACE organizations that choose to use contracted individuals or entities for marketing purposes must develop a method to document training has been provided.

- POs may now consider marketing activities that have been prohibited because current regulations have prohibited "contracting outreach efforts to individuals or organizations whose sole responsibility involves direct contact with the elderly to solicit enrollment."
- POs must confirm that any individual or entity, employed or contracted, that is engaged in marketing activity has been appropriately trained on PACE program requirements.
- POs must develop processes for oversight and monitoring of contracted individuals or entities who market on their behalf, and for documentation of training.

§460.82 Marketing, cont.

§460.82(e) Prohibited marketing practices. A PACE organization must not use the following marketing practices, which are prohibited:

…

(5) Unsolicited door-to-door marketing or other unsolicited means of direct contact, including calling or emailing a potential or current participant without the individual initiating contact.

- CMS clarifies that unsolicited means of direct contact beyond just door-to-door marketing are prohibited.
- CMS notes this prohibition is consistent across Medicare Advantage, Part D and PACE.
- POs should confirm their marketing practices are fully consistent with this requirement.

§460.82 Marketing, cont.

§460.82(f) has been deleted from §460.82. CMS is no longer requiring POs to establish, implement and maintain a documented marketing plan with measurable enrollment objectives and a system for tracking its effectiveness.

- CMS explains that it has determined this requirement to be redundant and that CMS has access to pertinent information through other account management activities.

§460.102 Interdisciplinary team (revised)

§460.102(b) Composition of interdisciplinary team. The interdisciplinary team must be composed of members qualified to fill, at minimum, the following roles, in accordance with CMS guidelines. One individual may fill two separate roles on the interdisciplinary team where the individual meets applicable state licensure requirements and is qualified to fill the two roles and able to provide appropriate care to meet the needs of participants.

(1) Primary care provider.

(2) Registered nurse.

(3) Master's-level social worker.

(4) Physical therapist.

(5) Occupational therapist.

(6) Recreational therapist or activity coordinator.

(7) Dietitian.

(8) PACE center manager.

(9) Home care coordinator.

(10) Personal care attendant or his or her representative.

(11) Driver or his or her representative.

§460.102 Interdisciplinary team, cont.

§460.102(c) Primary care provider. (1) Primary medical care must be furnished to a participant by one of the following:

(i) A primary care physician.

(ii) A community-based physician.

(iii) A physician assistant who is licensed in the State and practices within his or her scope of practice as defined by State laws with regard to oversight, practice authority and prescriptive authority.

(iv) A nurse practitioner who is licensed in the State and practices within his or her scope of practice as defined by State laws with regard to oversight, practice authority and prescriptive authority.

- The final rule does not alter the composition of the IDT with respect to the 11 roles that must be represented on the team. Rather, it provides flexibility with respect to how these roles are filled, allowing for one individual to fill two roles on the IDT. For POs that pursue this new flexibility, they must consider how to effectively document that all 11 IDT roles are represented as required.
- The primary care provider role on the IDT may now by filled by a primary care physician, community-based physician, NP or PA. BIPA 903 waivers are no longer required in order to do so. For POs that pursue this new flexibility, numerous considerations must be addressed to ensure the IDT is fully capable of fulfilling its responsibilities for assessment, care planning, service delivery, communication, etc. in compliance with federal regulatory requirements, state laws and regulatory requirements, etc.

§460.102 Interdisciplinary team, cont.

In §460.102(d) Responsibilities of interdisciplinary team, the requirement in §460.102(d)(3) that the members of the interdisciplinary team must serve primarily PACE participants has been deleted.

- POs will have greater flexibility to utilize part-time staff and community-based providers on the IDT.
- POs may want to evaluate their policies and procedures to determine if any modifications are necessary in light of this change.

§460.102 Interdisciplinary team, cont.

§460.102(e) Team member qualifications. The PACE organization must ensure that all members of the interdisciplinary team have appropriate licenses or certifications under State law, act within the scope of practice as defined by State laws, and meet the requirements set forth in §460.71.

- The final rule inserts a new §460.102(e) after §460.102(d) emphasizing the need for the PO to ensure all members of the IDT are appropriately licensed or certified under State law, act within their scope of practice and meet requirements of employees and contracted staff who furnish care directly to PACE participants.
- Codification of current policy.

§460.104 Participant assessment (revised)

§460.104(a) Initial comprehensive assessment—

(1) Basic requirement. The interdisciplinary team must conduct at initial in-person comprehensive assessment on each participant. The assessment must be completed in a timely manner in order to meet the requirements in paragraph (b) of this section.

(2) Members present. As part of the initial comprehensive assessment, each of the following members of the interdisciplinary team must evaluate the participant in person and develop a discipline-specific assessment of the participant's health and social status:

(i) Primary care provider.

(ii) Registered nurse.

(iii) Master's-level social worker.

(iv) Physical therapist.

(v) Occupational therapist.

(vi) Recreational therapist or activity coordinator.

(vii) Dietitian.

(viii) Home care coordinator

§460.104 Participant assessment, cont.

(3) Additional professional disciplines. At the recommendation of the interdisciplinary team, other professional disciplines (for example, speech-language pathology, dentistry, or audiology) may be included in the initial comprehensive assessment process.

- Changes to §460.104(a)(1) clarify that IDT members' initial assessments must be in-person and specify that all initial assessments must be completed in time for the IDT to complete the development of the participant's plan of care within 30 days of enrollment.
- Referring to §460.104(a)(2), the primary care provider (previously referred to primary care physician) is required to develop a discipline-specific assessment.
- The initial assessment still requires eight discipline-specific assessments.
- A change to 460.104(a)(3) stipulates that the interdisciplinary team (previously referred to individual team members) may recommend other disciplines be included in the initial assessment process.
- POs must ensure that assessment and care planning policies and procedures are consistent with the revisions to these requirements.

§460.104 Participant assessment, cont.

§460.104(b) Development of plan of care. Within 30 days of the date of enrollment, the interdisciplinary team must consolidate discipline-specific assessments into a single plan of care for each participant through team discussions and consensus of the entire interdisciplinary team. In developing the plan of care:

(1) If the interdisciplinary team determines that certain services are not necessary to the care of a participant, the reasoning behind this determination must be documented in the plan of care.

(2) Female participants must be informed that they are entitled to choose a qualified specialist for women's health services from the PACE organization's network to furnish routine or preventive women's health services.

- §460.104(b) specifies that the IDT must consolidate assessments into a single plan of care within 30 days of enrollment; the entire 11-member IDT much achieve consensus. Note: A parallel change is made in §460.106(a) requiring that a comprehensive plan of care must be developed within 30 days of the date of enrollment.
- "Team discussions" has replaced "discussion in team meetings" to give POs flexibility to determine the format and location of IDT discussions to "best meet the needs of PACE participants while not burdening the IDT by requiring these discussions to be held in face-to-face meetings."
- Referring to §460.104(b)(1), CMS explains that it expects the initial plan of care to reflect that the participant was assessed for all services even when a determination is made that certain services were not necessary at that time. POs will need to modify their policies and procedures for care plan documentation to reflect this change.
- POs must ensure that assessment and care planning policies and procedures are consistent with the revisions to these requirements.

§460.104 Participant assessment, cont.

§460.104(c) Semi-annual reassessment. On at least a semi-annual basis, or more often if a participant's condition dictates, the following members of the interdisciplinary team must conduct an in-person reassessment:

(1) Primary care provider.

(2) Registered nurse.

(3) Master's-level social worker.

(4) Other team members that the primary care provider, registered nurse and Master's level social worker determine are actively involved in the development or implementation of the participant's plan of care.

- Changes to §460.104(c) again replace "physician" with "provider" in §460.104(c)(1), eliminate the requirement for the RT/activity coordinator to perform a semi-annual assessment for all participants, and identifies the PCP, RN and MSW as the disciplines that determine if additional team members must conduct semi-annual reassessments based on their active involvement in the development or implementation of a participant's plan of care. POs must establish a process for making these determinations that ensures adequate documentation.
- In addition, changes in §460.104(c) eliminate references to annual reassessments. It is no longer required that a PT, OT, dietitian and home care coordinator must conduct an annual reassessment for all participants. On at least a semi-annual basis, the PCP, RN and MSW will perform in-person reassessments and determine if additional team members must conduct reassessments.
- POs will have to carefully consider the implications of these changes on their processes for scheduled reassessments and revise their policies and procedures accordingly.

§460.104 Participant assessment, cont.

§460.104(d) Unscheduled reassessments. In addition to semiannual reassessments, unscheduled reassessments may be required based on the following:

(1) A change in participant status. If the health or psychosocial status of a participant changes, the members of the interdisciplinary team listed in paragraph (c) of this section must conduct an in-person reassessment.

- As a result of this change the PCP, RN, MSW and other team members that they determine are actively involved in the development or implementation of the participant's plan of care must conduct an in-person assessment. (This is in contrast to 8 IDT members (primary care physician, RN, MSW, PT, OT, RT/activity coordinator, dietitian, HCC) who were previously required to perform an assessment in response to a change in participant status.)
- POs will have to carefully consider the implications of this change on their processes for unscheduled reassessments due to change in health status and revise their policies and procedures accordingly.

§460.104 Participant assessment, cont.

§460.104(d)(2) At the request of the participant or designated representative. If a participant (or his or her designated representative) believes that the participant needs to initiate, eliminate, or continue a particular service, the appropriate members of the interdisciplinary team, as identified by the interdisciplinary team, must conduct a reassessment. The interdisciplinary team member(s) may conduct the reassessment via remote technology when the interdisciplinary team determines that the use of remote technology is appropriate and the service request will likely be deemed necessary to improve or maintain the participant's overall health status and the participant or his or her designated representative agrees to the use of remote technology.

(i) An in-person reassessment must be conducted:

(A) When participant or his or her designated representative declines the use of remote technology.

(B) Before a PACE organization can deny a service request.

…

- It remains the case that the IDT determines which members of the IDT must conduct a reassessment in response to a service request.
- In contrast to initial assessments, scheduled reassessments and unscheduled reassessments due to change in health status which all must be done in-person, under certain circumstances, unscheduled reassessments in response to service requests may be conducted via remote technology, e.g., telephone, video conferencing, live instant messaging, chat software or other media that allow sufficiently direct and interactive communication. POs will want to consider how this option may be integrated into their policies and procedures for unscheduled reassessments related to service requests.
- Note: all other requirements related to SDRs are unchanged, e.g., timeframes, requirements for notification, etc.

§460.106 Plan of care (revision)

§460.106(b) Content of plan of care. The plan of care must meet the following requirements:

(1) Specify the care needed to meet the participant's medical, physical, emotional, and social needs, as identified in the initial comprehensive assessment.

(2) Identify measurable outcomes to be achieved.

(3) Utilize the most appropriate interventions for each care need that advances the participant toward a measurable goal and outcome.

(4) Identify each intervention and how it will be implemented.

(5) Identify how each intervention will be evaluated to determine progress in reaching specified goals and desired outcomes.

- POs must ensure that plans of care meet the expanded regulatory requirements in (3)-(5) above and revise policies and procedures as needed. POs should consult with their EHR vendors to ensure care plan documentation is consistent with these requirements.
- POs must revise policies and procedures to reflect the new requirement to finalize initial care plans within 30 days of enrollment.
- POs must revise policies and procedures for initial care plan to address new requirement to document reasoning behind IDT's determination that certain services are not necessary to care of participant.

§460.116 Explanation of rights (revised)

§460.116(c) Display. The PACE organization must meet the following requirements:

(1) Write the participant rights in English, and in any other principal languages of the community, as determined by the State in which the PACE organization is located. In the absence of a State standard, a principal language of the community is any language that is spoken by at least 5 percent of the individuals in the PACE organization's service area.

(2) Display the PACE participant rights in a prominent place in the PACE center.

- POs which have no state standards for principal languages must determine which principal languages apply and make the participant rights available in these languages.
- POs must ensure that PACE participant rights are identified as such and prominently displayed in the PACE center.

Subpart H—Quality Improvement
§460.130 General Rule (revised)

§460.130 General rule.

(a) A PACE organization must develop, implement, maintain, and evaluate an effective, data-driven quality improvement program.

(b) The program must reflect the full range of services furnished by the PACE organization.

(c) A PACE organization must take actions that result in improvements in its performance in all types of care.

(d) A PACE organization must meet external quality assessment and reporting requirements, as specified by CMS or the State administering agency, in accordance with §460.202.

- In §460.130, throughout Subpart H and entire 42 CFR part 460, "quality assessment and performance improvement" has been replaced with "quality improvement." POs should update written materials as needed to reflect this change.
- §460.130(d) is not a new requirement but has been moved from §460.140 to consolidate the general requirements of a PO's quality improvement program in the same section.

§460.132 Quality improvement plan (revised)

§460.132(a) Basic rule. A PACE organization must have a written quality improvement plan that is collaborative and interdisciplinary in nature.

- The revision to §460.132(a) was made to emphasize the requirement for a QI plan that is collaborative and interdisciplinary. POs should update materials as needed to reflect this change.

§460.150 Eligibility to enroll in a PACE program (revised)

§460.150(c) Other eligibility requirements.

(1) At the time of enrollment, an individual must be able to live in a community setting without jeopardizing his or her health or safety.

(2) The State administering agency criteria used to determine if an individual's health or safety would be jeopardized by living in a community setting must be specified in the program agreement.

- The change to §460.150(c) clarifies that the eligibility criteria used to determine health and safety in the community must be established by the SAA.
- This change reflects current practice and should not require action on the part of the PO.

§460.154 Enrollment agreement (revised)

§460.154 Enrollment agreement. If the potential participant meets the eligibility requirements and wants to enroll, he or she must sign an enrollment agreement which contains, at a minimum, the following information:

…

(i) Notification that enrollment in PACE results in disenrollment from any other Medicare or Medicaid prepayment plan or optional benefit. Electing enrollment in any other Medicare or Medicaid prepayment plan or optional benefit, including the hospice benefit, after enrolling as a PACE participant is considered a voluntary disenrollment from PACE. If a Medicaid-only or private pay participant becomes eligible for Medicare after enrollment in PACE, the participant will be disenrolled from PACE if he or she elects to obtain Medicare coverage other than from the participant's PACE organization.

…

- This change in the content of the enrollment agreement will require that POs update their enrollment agreements accordingly.

§460.156 Other enrollment procedures (revised)

§460.156(a) Items a PACE organization must give a participant upon enrollment. After the participant signs the enrollment agreement, the PACE organization must give the participant the following:

(1) A copy of the enrollment agreement.

(2) A PACE membership card that indicates that he or she is a PACE participant and that includes the phone number of the PACE organization.

(3) Emergency information to be posted in his or her home identifying the individual as a PACE participant and explaining how to access emergency services.

- Changes to §460.156(a) eliminate the requirement in §460.156(a)(4) for a PO to give stickers to newly enrolled participants for their Medicare and Medicaid cards. POs must change their practices accordingly.
- Changes to §460.156(a)(2) specify that the PACE membership card should indicate that its holder is a PACE participant and include the phone number of the PACE organization. POs must ensure that their membership cards meet revised regulatory requirements.

§460.162 Voluntary disenrollment (revised)

§460.162 Voluntary disenrollment.

(a) Effective date. A participant's voluntary disenrollment is effective on the first day of the month following the date the PACE organization receives the participant's notice of voluntary disenrollment.

(b) Reasons for voluntary disenrollment. A PACE participant may voluntarily disenroll from the program without cause at any time.

(c) Responsibilities of PACE organization. A PACE organization must ensure that its employees or contractors do not engage in any practice that would reasonably be expected to have the effect of steering or encouraging disenrollment of participants due to a change in health status.

- Depending on their current voluntary disenrollment procedures, POs may need to modify these policies and procedures, particularly with respect to effective date of voluntary disenrollment. Consultation with SAA to coordinate Medicaid disenrollment from PACE may be required.
- To comply with new §460.162(c), POs should consider options for implementing this requirement, e.g., staff education and updates to training materials, contract addendums, etc. CMS reminds POs in preamble that steering or encouraging a participant's disenrollment in response to a change in health status is behavior subject to sanctions under newly numbered §460.40(a)(3).

§460.164 Involuntary disenrollment (revised)

§460.164 Involuntary disenrollment.

(a) Effective date. A participant's involuntary disenrollment occurs after the PACE organization meets the requirements set forth in this section and is effective on 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.

- This timeframe provides a participant a minimum 30 days to respond to the PO's proposed disenrollment action, should he or she disagree, as well as to coordinate a transition to other care and services.
- POs should revise their involuntary disenrollment policies accordingly.

§460.164 Involuntary disenrollment, cont.

§460.164(b) Reasons for involuntary disenrollment. A participant may be involuntarily disenrolled for any of the following reasons:

(1) The participant, after a 30-day grace period, fails to pay or make satisfactory arrangements to pay any premium due the PACE organization.

(2) The participant, after a 30-day grace period, fails to pay or make satisfactory arrangements to pay any applicable Medicaid spenddown liability or any amount due under the post-eligibility treatment of income process, as permitted under §§460.182 and 460.184.

(3) The participant or the participant's caregiver engages in disruptive or threatening behavior as described in paragraph (c) of this section.

…

- §§460.164(b)(2) and (3) establish two new reasons for which the PO may involuntary disenroll a participant. As with all involuntary disenrollments, notice of involuntary disenrollment may only be given to a participant after the SAA has been notified and determined that the grounds for the disenrollment documented by the PO are acceptable. POs must update their policies and procedures consistent with these changes.
- New §460.164(c)(2) defines disruptive or threatening behavior on the part of a participant's caregiver as, "behavior that jeopardizes the participant's health or safety, or the safety of the caregiver or others." As is the case with disruptive or threatening behavior on the part of a participant, in situations involving a participant's caregiver's disruptive or threatening behavior, the PO must document reasons for proposing to disenroll the participant and all efforts to remedy the situation.

§460.168 Reinstatement in other Medicare and Medicaid programs (revised)

§460.168 Reinstatement in other Medicare and Medicaid programs.

To facilitate a participant's reinstatement in other Medicare and Medicaid programs after disenrollment, the PACE organization must do the following:

(a) Make appropriate referrals and ensure medical records are made available to new providers within 30 days.

…

- Change replaces "in a timely manner" with "within 30 days." POs should ensure their policies and procedures are consistent with this change.

§460.190 Monitoring during trial period (revised)

§460.190(b) Scope of review. The review includes the following:

(1) An onsite visit to the PACE organization, which may include, but is not limited to, observation of program operations.

(2) Detailed analysis of the entity's substantial compliance with all significant requirements of sections 1894 and 1934 of the Act and this part, which may include review of marketing, participant services, enrollment and disenrollment, and grievances and appeals.

…

- Clarifies that CMS has flexibility in its use of technology to conduct oversight and monitoring activities remotely vs. on-site.
- Changes do not substantively change the authority that CMS and the SAA have had and continue to have to conduct oversight related to all statutory and regulatory requirements of POs. Changes makes regulatory language more consistent with statute in Sections 1894 and 1934 of Social Security Act.
- Note: No change to frequency of audits during initial three-year trial period, i.e., annually.

§460.192 Ongoing monitoring after trial period (revised)

§460.92(b) CMS in cooperation with the State administering agency will conduct reviews of the operations of PACE organizations as appropriate, as determined by a risk assessment of each PACE organization which takes into account the PACE organization's performance level and compliance with the significant requirements of section 1894 and 1934 of the Social Security Act and this part.

- Change allows CMS greater flexibility with respect to timing of audits subsequent to the trial period. No longer will such audits be required to take place "at least every two years." Rather, the frequency of audits will be determined on the basis of a risk assessment of each PO that takes into account a number of factors, e.g., length of time between audits, past performance, PACE Quality Data, etc.

§460.194 Corrective action (revised)

§460.194(a) A PACE organization must take action to correct deficiencies identified by CMS or the State administering agency through the following:

(1) Ongoing monitoring of the PACE organization.

(2) Reviews and audits of the PACE organization.

(3) Complaints from PACE participants or caregivers.

(4) Any other instance CMS of the State administering agency identifies programmatic deficiencies requiring correction.

- Clarifies that POs must take action to correct deficiencies in response to all of the circumstances listed in §460.194(a)(1-4), not only in response to reviews as suggested by the previous language.

§460.196 Disclosure of review results (revised)

§460.196(d) The PACE organization must make the review results available for examination in a place readily accessible to participants, their families, their caregivers, and their authorized representatives.

- CMS' intent is for POs to make review results available not only to participants, but also to other individuals who may be making decisions about PACE participants' care.
- POs must ensure that review results are available consistent with this requirement.

§460.200 Maintenance of records and reporting of data (revised)

§460.200(f) Retention of records. (1) A PACE organization must retain records for the longest of the following periods:

(i) The period of time specified in State law.

(ii) Ten years from the last entry date.

(iii) For medical records of disenrolled participants, 10 years after the date of disenrollment.

…

- With this change the minimum period of time that a PO must retain records has increased from 6 to 10 years.
- POs must modify their record retention policies and procedures consistent with this change.

Questions??