SECTION-BY-SECTION SUMMARY OF PROPOSED CHANGES TO PACE REGULATION, 42 CFR Part 460, AND REQUEST FOR INPUT FROM NPA MEMBERS
Prepared by National PACE Association
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On August 11, 2016, CMS released a proposed rule to update and revise existing requirements in 42 CFR Part 460 for Programs of All-inclusive Care for the Elderly (PACE) under the Medicare and Medicaid programs with the objective of revising existing requirements to: (1) strengthen protections and improve care for beneficiaries, and (2) provide administrative flexibility and regulatory relief for PACE organizations. The proposed rule also would remove outdated information from the current regulation and codify existing practices, e.g. marketing guidelines.

Following is a section-by-section summary of CMS' proposed changes to current PACE regulatory requirements along with a description of CMS' rationale for the proposed changes, and related questions intended to solicit input from NPA members. Your responses to our questions and any additional feedback you provide will be used by NPA staff and the regulations subcommittee of the NPA public policy committee to develop NPA's draft response to CMS' request for comment on the proposed rule. This draft will be shared with NPA members for further comment. The page numbers below relate to the version of the proposed rule posted on the Federal Register public inspection page: https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-19153.pdf. If you have questions regarding the information presented below, please contact Chris van Reenen at chrisvr@npaonline.org or (703) 535-1568.

Section of Proposed Rule and Corresponding Page Numbers	Summary of Proposed Change	CMS' Rationale for Proposed Change	Questions to NPA Members (please do not hesitate to provide additional feedback beyond answering the questions listed below)
Proposed Global Change Regarding Quality Assessment and Performance Improvement (pp. 16-17)	Proposal to replace all references in 42 CFR Part 460 to "quality assessment and performance improvement" in the PACE regulation with "quality improvement." This is a change in terminology only.	"Quality improvement" is term commonly used among PACE organizations (POs), State Administering Agencies, CMS and the industry when referring to quality assessment and performance improvement. Also, "quality improvement" is term used in other CMS programs.	
Subpart A – Basis, Scope, and Definition (§460.3) (pp. 17-18 and p. 132)			
Proposed Part D Program Requirements (§460.3) (pp. 17-18 and p. 132)	Proposal to add new section §460.3 Part D program requirements. Under §460.3, POs offering qualified prescription drug coverage and meeting the definition of a Part D plan sponsor must abide by all applicable Part D program requirements in part 423. Under proposed change, current waivers of Part D regulations for POs would continue to apply.	Current PACE regulation does not reference Part D program requirements and the requirement that POs offering qualified prescription drug coverage and meeting the definition of a Part D plan sponsor must comply with applicable Part D requirements.	

Subpart B – PACE Organization Application and Waiver Process (§§460.10, 460.12, 460.18, 460.20, 460.22, 460.26, 460.28) (pp. 18-33 and pp. 132-137)			
Purpose (§460.10) (p. 18 and pp. 132-133)	Proposal to expand description of applications procedures for PACE to include both the initial PACE application process and the application process for expanding an existing service area and/or adding a new PACE center.	Current PACE regulation does not speak to the application processes for expanding an existing service area and/or adding a new PACE center. Intent of change is to specify that an application process is required of both (1) entities seeking to become POs, and (2) POs seeking to expand a geographic service area and/or add a new PACE center.	
Application Requirements (§460.12) (pp. 18-23 and pp. 133-134)	Proposal to expand §460.12(a) to include requirement for POs seeking to expand their service area and/or open a new PACE center to submit a complete application describing how they will meet all requirements of part 460. Currently §460.12(a) speaks only to application requirement for entities seeking to become POs. In §460.12(a), proposal to add "in the form and manner specified by CMS" when describing the submission to CMS of a complete application to become a PO or to expand a service area and/or add a PACE center. Proposal to delete §460.12(a)(2) related to "priority consideration" and "special consideration" in processing of applications. In 460.12(b), proposal to revise language to specify that applications must include an assurance from the State administering agency (SAA) that the SAA considers initial applicant to be qualified to be a PO and is willing to enter into a PACE program agreement with applicant. Similarly, expansion applications also must include an assurance from the SAA that it is willing to amend the PACE program agreement to include the new PACE center site and/or expand the PO's service area.	Intent of change is to specify that an application is required of POs seeking to expand geographic service area and/or add a new PACE center. To allow for submission of applications and supporting information in electronic formats. Move to use of electronic application process is consistent with Medicare Advantage (MA) and Part D application processes. These designations are no longer applicable. CMS believes that current regulatory language needs clarification to ensure applicants' understanding that assurance from SAA must be included in both initial and expansion applications.	To POs that have gone through expansion application process to expand geographic service area: Did your SAA verify that you had qualified administrative and clinical staff employed or under contract prior to furnishing services to participants in the expanded service area?

	Proposal to move language currently in §460.22 to new §460.12(c). §460.12(c) would require entities submitting initial applications and POs submitting applications to expand their service areas to describe in these applications their proposed service areas, and would allow CMS to exclude from a proposed service area an area already covered under another PACE program agreement. As a result of moving this requirement to new §460.12(c), §460.22 would be removed. Proposal to add new §460.12(d) to codify current practice of requiring a PO to have successfully completed its first trial period audit and, if applicable, implemented an acceptable corrective action plan before CMS and the State will approve a service area expansion or PACE center expansion application (Chapter 17, Sec. 20.4, PACE manual).	This is not a substantive change, but it enhances clarity of regulatory requirements. To ensure PO's operations have been audited for compliance with PACE regulatory requirements prior to expanding operations.	Do you think it is overly restrictive to require completion of first trial period audit and, if applicable, implementation of correction action plan before CMS and State will approve a service area or PACE center expansion? If so, what do you propose as alternative criteria to assure CMS of PO's capacity to expand its operations successfully?
CMS Evaluation of Applications (§460.18) (p. 23 and p. 134)	Proposal to modify language in §460.18 to: (1) clarify that CMS evaluates both initial and expansion applications, and (2) recognize that in evaluating an expansion application, CMS may consider additional information beyond what is included in the application, information obtained through on-site visits, or information obtained through the SAA, e.g., information obtained from the PO's financial reviews.	To recognize CMS' evaluation of both initial and expansion applications, and for expansion applications the availability of additional sources of information.	
Notice of CMS Determination (§460.20) (pp. 24-29 and pp. 134-136)	Proposal to modify §460.20 to describe requirements of CMS to notify both entities submitting initial applications and POs submitting expansion applications of its determination to approve or deny these applications. The current regulation refers only to CMS determinations on initial applications. In general, the proposed §460.20 is consistent with current regulatory requirements related to notice of CMS determinations for initial applications and guidance in Chapter 17 of the PACE manual for determinations on expansion applications. That is, for initial applications and	To include in the regulation the process by which CMS makes a determination on both initial and expansion applications and to clarify existing language.	NPA would appreciate members' input on barriers that would be created if CMS requires applicants to submit new applications if they don't respond to CMS' request for additional information within six months of submission of application.

	expansion applications to both expand a PO's service area AND add a new PACE center, CMS has 90 days to request additional information and, following the applicant's submission of additional information, 90 days to approve or deny the application. For expansion applications to either expand a service area OR add a new PACE center, the corresponding time frames are 45 days to request additional information and 45 days to approve or deny the application following the PO's submission of additional information. Lastly, CMS proposes to add a new §460.20(c)(2) stating that, "If more than 6 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."		
Submission and evaluation of waiver requests (§460.26) (pp. 29-30 and p. 136)	Proposal to change §460.26 to clarify requirements for waiver requests submitted by both POs and entities submitting applications to be POs. In both cases, waiver requests must be submitted through the SAA for initial review. The SAA then forwards waiver requests to CMS along with any concerns or conditions regarding the waiver. Waiver requests submitted by entities applying to be POs may be submitted in conjunction with PACE applications or separately.	Proposed changes are intended to clarify existing policy.	
Notice of CMS determination on waiver requests (§460.28) (pp. 30-33 and pp. 136-137)	§460.28 discusses the time frames for CMS determination and notification regarding approval or denial of waiver requests. Consistent with the current regulation, CMS is required to approve or deny a waiver request within 90 days of receipt; however, the proposed rule specifies that this shall be within 90 days of receipt of a complete waiver request. CMS clarifies that a waiver request is considered complete only when CMS receives all information necessary to make a determination regarding approval or denial. If additional information is required, CMS will request it of the PO or PACE applicant. CMS also introduces the concept of	Proposed changes clarify time frame for CMS' response to waiver requests, including the steps that CMS will take if the waiver request does not provide sufficient information for CMS to make a determination on the waiver. Proposed changes also clarify what would happen if the time frame for a determination on a waiver request precedes the time frame for a determination on an initial PACE application.	

	"conditional approval" of a waiver request for those waiver requests made in the context of pending provider applications. In situations where an application has not yet been approved, a waiver request, if not denied, will receive a conditional approval. Finally, CMS modifies the current requirement related to withdrawing approval of a waiver. CMS proposes that withdrawing approval must be done "in consultation with the SAA" and that, if approval is withdrawn, CMS must notify the PO or PACE applicant and the SAA.		
Subpart C – PACE Program Agreement (§460.32) (pp. 33-35 and pp. 137-138)			
Content and terms of PACE program agreement (§460.32) (pp. 33-35 and pp. 137-138)	Proposal to modify the current requirement in §460.32(a)(12) that requires the Medicaid capitation rate to be included in the PACE program agreement. The proposed change would allow for either the Medicaid capitation rate(s) OR the Medicaid payment rate methodology to be included in program agreement. CMS also seeks comments regarding other modifications to the required content of the PACE program agreement. CMS is particularly interested in comments regarding the need for capturing the level of detail currently required within the agreement itself, along with updated information as may be necessary throughout the contract period.	CMS' intent is to address challenges with including actual Medicaid rates resulting from rate-setting methodologies that call for risk adjustment, performance incentive payments, etc. In these situations, rates may be different for individual participants or dependent on program performance. Also, removing the requirement for actual rates in the program agreement would address operational challenges associated with updating the program agreement.	What modifications do you suggest to PACE program agreement? If advocating to delete content that is currently required from program agreement, recommend alternative ways to provide information to CMS and SAA.
Subpart D – Sanctions, Enforcement Actions, and Terminations (§§460.40, 460.46) (pp. 35-37 and pp. 138-140)			
Violations for which CMS may impose sanctions (§460.40) (pp. 35-36 and pp. 138-140)	As an alternative to terminating a PO's program agreement, proposal to clarify CMS' authority to impose sanctions, i.e., suspend enrollment or payment, or impose civil money penalties, in circumstances that currently warrant program termination under §460.50, e.g., uncorrected failure to comply substantially with conditions of the PACE program or with the terms of the PACE agreement, and inability to ensure the health and	Proposed change would make PACE rule consistent with Medicare Advantage program enforcement authorities by allowing CMS the discretion to take enforcement actions in form of sanctions or CMPs, in addition to taking the most extreme action of termination of the PACE program agreement.	

	safety of participants, such as the presence of deficiencies that CMS or the SAA determine cannot be corrected.		
Civil money penalties (§460.46) (pp. 36-37 and p. 140)	Proposal to add a Note to §460.46(a) indicating that civil money penalty amounts will be adjusted for inflation in accordance with the Federal Civil Penalties Inflation Adjustment Act of 2015.	The 2015 Act requires agencies to adjust civil money penalties annually for inflation.	
Subpart E – PACE Administrative Requirements (§§460.60, 460.62, 460.63, 460.64, 460.68, 460.70, 460.71, 460.72, 460.82) (pp. 37-60 and pp. 140-146)			
PACE organizational structure (§460.60) (pp. 37-42 and pp. 140-141)	Proposal to remove the requirement that POs be not-for-profit entities consistent with the PACE statute and the findings in the May 19, 2015 report to Congress. Proposal to revise current requirements related to notification of changes in the organizational structure of a PO. More specifically, proposal to apply provisions of Medicare Advantage regulations at §422.550 requiring at least 60 days' advance notice to both CMS and the SAA of PO changes of ownership. CMS further clarifies that all requirements in 42 CFR part 422, subpart L (Effect of Change of Ownership or Leasing of Facilities During Term of Contract) apply to POs in change of ownership scenario. CMS' proposed changes to §460.60 are consistent with the memo CMS released on change of ownership dated February 18, 2016.	CMS is updating the PACE regulation to reflect that the study of the experience of for-profit entities found it was not different from that of not-for-profit PACE organizations as reported in the May 19, 2015 report to Congress. CMS believes that application of proposed requirements is necessary to ensure that an entity acquiring a PO meets all PACE requirements and will be able to continue providing quality care to the participants of the PO, and to reflect the change of ownership in CMS' systems.	
Governing body (§460.62) (pp. 42-43 and p. 141)	Proposal to clarify the responsibilities of the PACE governing body by specifically referencing that it has full legal authority and responsibility for the PACE organization's quality improvement program as described in §460.130. Proposal to include among the governing body's responsibilities adoption and implementation of	To clarify the governing body's responsibility to create and foster an environment that provides quality care that is consistent with participant needs and the program mission. Under proposed §460.63 CMS is requiring that all POs adopt and implement effective compliance oversight. CMS	

	effective compliance oversight as described in §460.63 (directly below).	is assigning responsibility for compliance oversight to the PO's governing body.	
Proposed Compliance Oversight Requirements (proposed new §460.63) (pp. 43-46 and pp. 141-142)	Proposal to adopt compliance oversight requirements in new section §460.63 of the PACE regulation. POs would be required to have a compliance oversight program responsible for monitoring and auditing their organization for compliance with CMS regulations. Additionally, POs would be required to have measures that prevent, detect and correct non-compliance with CMS's program requirements and measures that prevent, detect, and correct fraud, waste and abuse. CMS is proposing that the two elements of a Part D compliance program that are required of POs participating in Part D will become compliance oversight requirements for the PO as a whole. CMS proposes that the compliance oversight program in PACE include, at a minimum: (1) the establishment and implementation of an effective system for routine monitoring and identification of compliance risks, which should include internal monitoring and audits and, as appropriate, external audits, to evaluate the PO, including contractors, compliance with CMS requirements and the overall effectiveness of the compliance oversight program; and (2) the 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-evaluation and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensuring ongoing compliance with CMS requirements. Further, CMS proposes requirements for POs to: (1) conduct a timely and reasonable inquiry if evidence of misconduct relating to payment or delivery of items or services is discovered, (2) conduct appropriate corrective action in response to potential violations, and (3) have procedures to voluntarily self-report potential fraud or	CMS believes that requiring these compliance oversight provisions will balance the duty of a PO to ensure compliance with CMS requirements with the need for flexibility as a provider of service.	To what extent do POs believe they already comply with some or all of additional requirements under §460.63. Please be specific. As a result of your experience implementing these requirements for Part D benefits, what benefits and challenges do you anticipate in implementing compliance oversight requirements across all services provided by your PO? What would a reasonable effective date be for this requirement? CMS estimates a one-time cost of approximately $8900 for each PO to develop written material and documents necessary for internal auditing and monitoring purposes. CMS estimates an additional cost of approximately $12,000 per year to update materials and for routine identification of risks. Are these burden estimates reasonable?

	misconduct to CMS and the SAA. These elements should already have been implemented for Part D benefits; CMS proposes to extend these requirements to cover all services provided by POs. CMs proposes to verify compliance with requirements under §460.63 through monitoring or auditing of the PO.		
Personnel qualifications for staff with direct participant contact (§460.64) (pp. 46-48 and pp. 142-143)	Proposal to no longer limit the PO to employing or contracting with staff who have one year of experience with a frail or elderly population if they meet all other qualifications for hire under 460.64(a). For individuals without one-year prior experience, the PO would provide training on working with a frail or elderly population, based on industry standards, upon hiring. In addition, proposal to no longer require CMS to approve POs' competency evaluation programs under §460.64(a)(4). As a consequence of these proposed changes, each member of the PACE organization's staff (employee or contractor) that has direct contact with participants would need to meet the following conditions: (1) be legally authorized (e.g., currently licensed, if applicable) to practice in the State; (2) act within the scope of his/her authority to practice; (3) have one year prior experience or, if less than one year but meets all other requirements, must receive appropriate training from the PO on working with a frail or elderly population upon hiring; (4) meet a standardized set of competencies for the specific position description established by the PO that meet current industry standards; and (5) are medically cleared for communicable diseases and have all immunizations up-to-date before engaging in direct participant contact.	To allow for greater flexibility in hiring/contracting of staff that provide direct participant care by no longer prohibiting POs from hiring/contracting individuals who would be qualified if not for the one-year prior experience requirement. By eliminating the requirement for CMS to approve POs' competency evaluation programs, POs will have greater flexibility in modifying these programs to stay abreast of current industry standards and CMS' administrative burden will be reduced.	
Program integrity (§460.68) (pp. 48-51 and pp. 143-144)	In an attempt to more effectively mitigate the risks that employing or contracting with certain individuals and organizations with prior convictions may pose to the	Although CMS continues to believe it is important to POs to consider an individual's prior criminal convictions for physical, sexual, drug, or alcohol abuse or use and	

	PACE program, CMS proposes to modify §460.68(a)(3) to allow POs to hire and contract with individuals who have had issues in their past that do not pose a risk to the PACE program. POs will have greater discretion in determining whether a prior conviction poses a foreseeable threat to participants and no longer be required to disqualify individuals with prior convictions across the board. For example, POs would have the discretion to hire an individual with a conviction related to underage drinking who has not had a conviction as an adult, if otherwise qualified, and would pose no foreseeable threat to participants.	potential risk to participants, CMS does not want to limit excessively POs' ability to hire or contract with qualified individuals as a result of current requirements under §460.68(a)(3). This approach is consistent with requirements applied to long-term care facilities.	
	CMS proposes to replace the current reference in §460.68(a)(3) to "physical, sexual, drug, or alcohol abuse" with "physical, sexual, drug, or alcohol abuse or use."	To parallel the terminology used in criminal statutes, which often do not use the term "abuse" to describe the misconduct at issue, and also does not take into account criminal convictions that could be related to drug or alcohol use, such as DUIs, or drunken and disorderly conduct.	
	In addition, CMS proposes to add two additional limitations ((a)(4) and (5)) on POs employing or contracting with individuals or organizations: (1) PO must not employ or contract with individuals or organizations 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 aid registry concerning abuse, neglect, mistreatment of residents, or misappropriation of their property, and (2) PO must not employ or contract with individuals or organizations who have been convicted of crimes listed in section 1128(a) of the Social Security Act. Crimes listed in 1128(a) include: (1) conviction of program-related crimes; (2) conviction relating to patient abuse; (3) felony conviction relating to health care fraud; or (4) felony conviction relating to controlled substance.	CMS believes that new restrictions under §460.68(4) and (5) are necessary to protect participants in the PACE program consistent with protection of residents in long term care facilities.	CMS is requesting comment on whether they should extend this provision to restrict hiring with respect to those with certain criminal justice histories to include those with current restraining orders against them.

Contracted services (§460.70) (pp. 51-53 and pp. 144-145)	CMS reiterates the requirement that all administrative or care-related services, except for emergency services, that are not furnished directly by a PO must be obtained through contracts that meet the requirements of §460.70. For future rulemaking (not part of this current cycle of rulemaking), CMS is asking for input on whether contracted services authorized by the PO or services provided directly by the PO should comply with the Home and Community-Based Settings (HCBS) rule when non-institutional settings are used to house and/or to provide services to PACE participants, provided they do not conflict with requirements under §460. More specifically, CMS is soliciting comments on: (1) Adding a new paragraph §460.70(b)(1)(iv) stating, a contractor must comply with the HCBS rule when non-institutional settings are used to house, provide services to, or house and provide services to PACE participants, provided they do not conflict with requirements under §460. (2) Adding a new paragraph §460.98(b)(4) stating, the PO must comply with the HCBS rule when non-institutional settings are used to house, provide services to, or house and provide services to PACE participants, provided they do not conflict with requirements under §460. In addition, CMS proposes to clarify that existing contractor requirements under §460.70(d)(5)(vi) through (ix) apply specifically in the context of contracts where the PO chooses to contract with individuals as IDT members or key administrative staff. These requirements include: (1) agree to perform all duties related to its position as specified in this part, (2) participate in interdisciplinary team meetings as required, (3) agree to be accountable to the PO, and (4)	The HCBS Rule applies to many different Medicaid authorities including state plan services, and 1915(c), 1915(i) and 1915(k) waivers. Because POs support the majority of participants in non-institutional settings, CMS is seeking comments on whether or not CMS should apply the HCBS requirements to POs. The additional proposed change, which is the only change to this section being considered in current rulemaking process, is intended to make the regulation clearer.	CMS is seeking input on whether contracted services authorized by the PO or services operated directly by the PO should comply with the HCBS regulation at §441.301(c)(4). Please see pp. 25-26 for the text of §441.301(c)(4) and (5). Please review these requirements and share your feedback.

	cooperate with the competency evaluation program and direct participant care requirements.		
Oversight of direct participant care (§460.71) (pp. 53-54 and p. 145)	Proposal to make technical, non-substantive changes to language in current §460.71(a)(1). In addition, CMS is proposing change to language in §460.71(b)(4) requiring that PACE staff who have direct participant contact must be medically cleared for communicable disease and have all immunizations up-to-date before engaging in care. This is in contrast to current language in §460.71(b)(4) which requires staff to be "free of communicable diseases." In addition, proposal to move requirements in §460.66(b) and (c) to develop a training program for personal care attendants to establish their competency in furnishing personal care services and for personal care attendants to exhibit competency before performing services independently to §460.71(c) and (d).	Change to language in §460.71(b)(4) makes it consistent with language in §460.64(a)(5). To consolidate requirements regarding training of staff and competency evaluations for employees and contracted staff furnishing care directly to participants in a single section §460.71.	Are there concerns with change to language requiring medical clearance? Do we need further clarification as to what this requires of POs for contracted staff vs. staff of contracted entities?
Physical environment (§460.72) (pp. 54-55)	CMS explains that it is not proposing any changes to §460.72 as part of the current rulemaking process. CMS does, however, remind readers that CMS had previously published a proposed rule that, if finalized, would affect the PACE requirements in §460.72. This proposed rule, published in the Federal Register on 12/27/2013 and titled "Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers; Proposed Rule" would create a new §460.84.		
Marketing (§460.82) (pp. 55-60 and pp. 145-146)	Proposal to define "principal languages of the community" in §460.82(c)(1) for POs in states that do not have an established standard for when a language is considered to be a principal language of the community. CMS' proposed definition is, "any language spoken in the home by at least 5% of the individuals in the PO's service area." As a consequence, per proposed §460.82(c)(1), POs would furnish printed marketing materials to prospective and current participants in	CMS uses a similar 5 percent language threshold for marketing materials in Medicare Advantage and believes threshold is appropriate for PACE.	What will impact be on POs of change to establish a standard for "principal language" in States where such a standard is not already determined?

	English and in any language spoken in the home by at least 5% of the individuals in the PO's service area. Source of info on principal languages is the U.S. Census Bureau's American Community Survey, and CMS proposes to communicate this information to POs via HPMS.		
	Proposal to modify §460.82(e)(3) to specify that gifts or payments to induce enrollment are prohibited, unless (1) the gifts are of nominal value as defined in CMS guidance (currently $15 or less per PACE Marketing Guidelines), (2) are offered to all potential enrollees without regard to whether they enroll in the PACE program, and (3) are not in the form of cash or other monetary rebates.	Limits on nominal value of gifts is consistent with limits under the Medicare Advantage and Part D programs.	Any questions regarding what gifts can be, e.g., are gift cards allowed? Are gift cards considered a "monetary rebate"?
	Proposal to replace current language in §460.82(e)(4) which prohibits POs from contracting outreach efforts to individuals or organizations whose sole responsibility involves direct contact with the elderly to solicit enrollment. Proposed §460.82(e)(4) would prohibit marketing by any individuals other than the employees of the PACE organization.	CMS believes that the differences between PACE, and MA and Part D warrant the limitation on POs' use of non-employed agents and brokers and the requirement that the PO may use only employees for marketing activities. CMS is seeking comments on whether proposed prohibition on use of independent agents and brokers is appropriate. More specifically, if commenters believe prohibition is inappropriate, they are asked to specify reasons for their use, describe how POs contemplate using agents and brokers, and identify protections POs have in place to ensure accurate information is provided to potential PACE participants.	
	Proposal to add language to §460.82(e)(5) specifying that all unsolicited means of direct contact are prohibited including: door-to-door marketing, telephone calls, emails, etc. This would extend prohibitions beyond door-to-door marketing and "cold calling" referenced in Marketing Guidelines to include emails and all other unsolicited means of direct contact.	CMS believes expanding prohibition on unsolicited means of direct contact is appropriate based on the vulnerability of the population served in PACE and increase in health care fraud. Proposed change is also consistent with MA marketing requirements.	

	Proposal to remove §460.82(f) which requires that POs establish, implement and maintain a documented marketing plan.	CMS believes that requirement for marketing plan is redundant and that information captured in the plan is attainable through account management activities, e.g., POs convey marketing strategy in meetings with CMS Account Managers, and marketing materials and messages are shared through the marketing submission and review process and CMS has a separate method for tracking enrollment data.	
Subpart F – PACE Services (§§460.98, 460.100, 460.102, 460.104, 460.106) (pp. 60-77 and pp. 146-151)			
Service delivery (§460.98) (pp. 60-62 and p. 146)	The only specific changes that CMS is proposing for §460.98 at this time is (1) to replace "PACE Center" with "PACE center" in §460.98(d), and (2) to replace "Pace center" with "PACE center" in §460.98(d)(3). In addition, to inform future rulemaking, CMS is requesting comment on potential changes to PACE center requirements and ways to revise current regulatory requirements to allow greater flexibility with regard to alternative care settings in which IDT members provide PACE services while still ensuring that PACE participants can receive the full range of services and benefits that has made PACE such a successful model for this population.		What alternative settings would support the IDT's effective operations and assure participants' access to services. What criteria do/would you use to identify participants who would benefit from care in an alternative setting.
Emergency care (§460.100) (p. 62 and pp. 146-147)	Proposal to make a technical revision to §460.100(e)(3)(i) to replace references to "POs" and "PO" with references to "PACE organizations" and "PACE organization."	To make regulatory language consistent throughout the PACE rule.	
Interdisciplinary team (§460.102) (pp. 62-69 and pp. 147-148)	Proposal to permit POs to allow one individual on the IDT fulfill a maximum of two separate roles when the individual meets applicable state licensure requirements and is qualified to fill each role and able to provide appropriate care to meet participants' needs. CMS and SAA monitoring will ensure that POs exercising this option are in compliance with all PACE requirements.	CMS is proposing this change to provide POs greater flexibility in recognition of difficulties that POs may face, particularly those in rural areas, in having a separate individual fill each of the 11 IDT roles.	

	Proposal to revise §460.102(b)(1) to specify that a primary care provider, rather than a primary care physician, must be part of the core IDT. In addition, CMS proposes to revise §460.102(c)(1) to permit primary medical care to be furnished by a primary care physician, a community-based physician, a physician assistant (provided certain requirements are met), or a nurse practitioner (provided certain requirements are met). These changes would allow POs to furnish primary care through these other types of primary care providers without having to request waiver authority. Physician assistants and nurse practitioners must be licensed in accordance with state law and practice within their scope of practice as defined by state laws with regard to oversight, practice authority, and prescriptive authority.	CMS is proposing these changes in recognition of evolving medical practices and technologies and with the belief that affording POs the flexibility to involve other non-physician practitioners to practice collaboratively with the PACE primary care physician would enable POs to accommodate more participants and expand their programs, without compromising quality of care.	Are there any concerns with regard to proposed language in §460.102(c)(1)(iii) and (iv) requiring physician assistants and nurse practitioners to be "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."
	CMS proposes to revise §460.102(d)(3) to exclude community-based primary care physicians from the requirement that IDT members primarily serve PACE participants. In addition, CMS is requesting comment on whether the requirement that IDT members primarily serve PACE participants in §460.102(d)(3) should be deleted entirely.	CMS proposes this change in recognition of the fact that community-based primary care physicians work outside of the PO.	Can POs provide specific examples of how "primarily serve" requirement has had detrimental effect on PO's ability to provide care, e.g., limited ability to hire qualified staff on part-time basis or led to unnecessary costs? How does "primarily serve" requirement impact newly operational POs with low enrollment? Are there any concerns with deleting §460.103(d) in its entirety? Would it be preferable to modify it somehow?
	CMS is requesting comment on possibility of deleting requirements in §460.102(b) related to the composition of the PACE IDT. Under this approach, CMS would expect the composition of the IDT could be tailored based on each individual participant and the PO would continue to assess the need for services and provide all necessary services.	CMS believes this alternative approach of deleting the IDT composition requirements in §460.102(b) could provide greater flexibility to POs without compromising the quality of care and invites public comment on the approach.	How would flexible IDT work operationally with different combinations of team members for different participants? How would care planning meetings be scheduled to maximize use of staff time?

Participant assessment (§460.104) (pp. 69-75 and pp. 148-150)	Proposal to clarify that IDT members must conduct their initial comprehensive assessments in person. CMS proposes to add "in-person" to §460.104(a)(1).	CMS' intent is to clarify existing requirement consistent with current practice.	
	Proposal to require that the initial comprehensive assessment must be completed in time to allow the IDT to complete development of the plan of care within 30 days of the date of enrollment.	CMS' intent is to make requirement for timing of assessments consistent with requirement for development of plan of care.	Do POs have any concerns regarding requirement to complete comprehensive initial assessment in time to allow the IDT to complete development of plan of care within 30 days of enrollment, e.g., in event participant is hospitalized within 30 days of enrollment?
	Proposal to replace reference to "primary care physician" in §460.104(2)(i) to "primary care provider" consistent with proposed changes under §460.102 above.	Proposed change acknowledges change in definition of primary care provider to include primary care physician, community-based primary care physician, NP and PA.	
	Proposal to make several minor changes to §460.104(a)(2), (3) and (4): §460.104(a)(2) – remove reference to IDT members initially evaluating participants "at appropriate intervals" §460.104(a)(3) – change language from "individual team members" to "the interdisciplinary team" and add "initial" before "comprehensive assessment" §460.104(a)(4) – Revise heading from "Comprehensive assessment criteria" to "Initial comprehensive assessment criteria" and specify that initial comprehensive assessment is "in-person."	Proposed changes improve clarity of requirements.	
	Proposal to change §460.104(b) to specify that plans of care must be completed within "30 days of the date of enrollment."	CMS wants to remove ambiguity of current requirement to "promptly" consolidate assessments into single plan of care and believes that 30 days balances the need for time to complete assessments with need to complete these activities within a reasonable amount of time.	Do POs have any concerns regarding requirement to complete development of plan of care within 30 days of enrollment?

	Proposal to change language in §460.104(b) requiring that assessments be consolidated into a plan of care through "discussions in team meetings." As an alternative, CMS is proposing "team discussions" to indicate that while there must be a team discussion, IDT members do not need to be physically present. The format (e.g., video conferencing, conference call or in-person meeting) and location of the discussion would be the PO's discretion. In §460.104(b)(1), CMS is proposing that if the IDT determines from its assessment that any services associated with the comprehensive assessment criteria listed in §460.104(a)(4) do not need to be included in a participant's plan of care, the IDT must document in the participant's plan of care the reasons such services are not needed and are not being included.	To provide greater flexibility in the format and location of IDT discussions.	
	Although CMS is not proposing any changes to the list of IDT members who must perform initial in-person comprehensive assessments, CMS is proposing numerous and substantive changes to requirements in §460.104(c) related to periodic reassessments. Currently, PACE participants are reassessed semiannually, i.e., at least once every six months. These semi-annual reassessments involve, at a minimum, the PCP, RN, MSW, recreational therapist/activity coordinator, and other IDT members actively involved in the development or implementation of the participant's plan of care. At least annually, participants must be reassessed by the PT, OT, dietitian and home care coordinator. As an alternative, CMS is proposing to delete the requirement for annual reassessments by the PT, OT, dietitian and home care coordinator. Further, CMS is proposing that semi-annual reassessments be required of the PCP, RN, MSW and any other IDT members actively involved in the development or	To reduce burden of current requirements related to scheduled reassessments and to allow POs to allocate their resources more efficiently, while still meeting the care needs of participants.	How will POs ensure that other IDT members actively involved in the development or implementation of the participant's plan of care, as determined by PCP, RN and MSW, perform scheduled reassessments?

	implementation of the participant's plan of care, as determined by the PCP, RN and MSW. With respect to unscheduled reassessments, currently the following IDT members are required to perform an assessment in the event of a change in participant's health status: PCP, RN, MSW, PT, OT, RT, dietitian, home care coordinator and other disciplines at recommendation of IDT members. Currently, in response to a request of the participant or the participant's designated representative, appropriate members of the IDT, as identified by the IDT, are required to perform an assessment. In both these situations, CMS is proposing to change this list to: PCP; RN; MSW; and other team members actively involved in development or implementation of participant's plan of care, as determined by the PCP, RN and MSW.	To reduce burden of current requirements related to unscheduled reassessments and to allow POs to allocate their resources more efficiently, while still meeting the care needs of participants.	How will POs ensure that other IDT members actively involved in the development or implementation of the participant's plan of care, as determined by PCP, RN and MSW, perform unscheduled reassessments?
Plan of care (§460.106) (pp. 75-77 and pp. 150-151)	As explained above in the context of §460.104, CMS proposes that the plan of care be developed "within 30 days of the date of enrollment." CMS proposes that the IDT members identified in proposed §460.104(a)(2) must develop the care plan. This is a change from understanding of current requirements that all IDT members are involved in care plan development including PACE center manager; personal care attendant, or his or her representative; and driver, or his or her representative. CMS proposes adding new requirements under §460.106(b) to: (1) require that the plan of care utilize the most appropriate interventions for each of the participant's care needs that advances the participant toward a measurable goal and desired outcome; (2) require that the plan of care identify each intervention and how it will be implemented (interventions should be targeted, specific targeted, specific actions implemented	CMS' intent is to clarify which members of the IDT are required to develop the plan of care within 30 days. CMS' intent is to clarify the overall purpose, goal, creation, implementation and follow-up process of the plan of care, and to explicitly require POs to follow industry standards in developing and following care plan interventions.	Are there circumstances in which it would be impossible to complete plan of care within 30 days, e.g., if participant is hospitalized soon after enrollment? What, if any, additional requirements are proposed for POs? How do these requirements differ from those in current care planning guidance?

	to improve a participant's health care outcome); and (3) require that the plan of care identify how each intervention will be evaluated to determine progress in reaching specified goals and desired outcomes.		
Subpart G – Participant Rights (§§460.112, 460.116, 460.122) (pp. 77-80 and pp. 151-153)			
Specific rights to which a participant is entitled (§460.112) (pp. 77-78 and pp. 151-152)	CMS proposes to combine current §460.112(b)(1)(i) and (ii) into proposed §460.112(b)(1)(i) to state that information about PACE services will be provided "prior to and upon enrollment," and to redesignate §460.112(b)(1)(iii) as §460.112(b)(1)(ii). CMS proposes to make a technical change to §460.112(b)(3) by replacing "to be assisted" with "to be helped" in examining the results of the most recent review of the PO conducted by CMS or the SAA. CMS proposes to revise §460.112(c)(3) to state that the participant has the right to disenroll from the program at any time and have such disenrollment be effective the first day of the month following the date the PACE organization receives the participant's notice of voluntary disenrollment.	To simplify language and regulatory construction. To simplify the language. To specify requirements related to voluntary disenrollment consistent with current practice.	Is this change consistent with POs' current practice? Does this present any challenges to POs?
Explanation of rights (§460.116) (p. 79 and p. 152)	CMS proposes to specify that participant rights shall be written in both English and in any other principal languages of the community. If a state has not established a standard for making the principal language determination, participant rights must be written in those languages spoken in the home by at least 5% of the individuals in the PO's service area. If the State has such standards, the State's standards apply. CMs proposes to clarify §460.116(c)(2) requiring POs to display PACE participant rights in a prominent place in the PACE center.	CMS believes that the 5% standard is appropriate in States that don't have such standards for principal languages in the community. Further, this 5% standard is also being applied for marketing materials in §460.82. To clarify regulatory requirement.	

PACE organization's appeal process (§460.122) (p. 80 and pp. 152-153)	CMS proposes minor technical change to correct numbering.		
Subpart H – Quality Assessment and Performance Improvement (§§460.130, 460.132) (pp. 80-82 and pp. 153-154)			
General rule (§460.130) (pp. 80-81 and p. 153)	CMS proposes to move requirement in §460.140 to §460.130(d). This will result in removal of §460.140	To consolidate all of the general rules for quality improvement in §460.130.	
Quality assessment and performance improvement plan (§460.132) (pp. 81-82 and pp. 153-154)	CMS proposes to specify that the quality improvement plan referenced in §460.132(a) must be collaborative and interdisciplinary in nature.	CMS believes that a PO's quality improvement plan should reflect the collaborative and interdisciplinary approach in treatment of PACE participants in its improvement goals. Consistent with this, each time the PO's governing body develops a plan of action to improve or maintain the quality of care, the plan should focus on the collaborative and interdisciplinary nature of the PACE program. CMS believes that requiring a collaborative and interdisciplinary quality improvement plan will help POs identify and improve PACE quality issues more appropriately.	How would a requirement for the QI plan to be "collaborative and interdisciplinary" impact your PO's QI activities?
Subpart I – Participant Enrollment and Disenrollment (§§460.150, 460.152, 460.154, 460.156, 460.162, 460.164, 460.166, 460.168) (pp. 82-91 and pp. 154-158)			
Eligibility to enroll in a PACE program (§460.150) (pp. 82-83 and pp. 154-155)	CMS proposes to revise §460.150(c)(2) to include a reference to the SAA criteria used to determine if an individual's health or safety would be jeopardized by living in a community setting, to indicate that these criteria are developed by the SAA.	To codify existing policy in regulations.	
Enrollment process (§460.152) (p. 83 and p. 155)	CMS proposes to add, "in the form and manner specified by CMS" to the requirement in §460.152(b)(4) that POs must notify CMS and the SAA if a potential participant is denied enrollment because his or her health or safety would be jeopardized by living in a community setting.	To allow for these notifications to be required in electronic format.	
Enrollment agreement (§460.154) (p. 83 and p. 155)	CMS proposes to include language in §460.154(i) specifying that if a Medicaid-only or private pay PACE participant becomes eligible for Medicare after enrollment in PACE, he/she will be disenrolled from	To clarify consequences of electing to obtain Medicare coverage outside the PO for Medicaid-only or private pay PACE participants newly eligible for Medicare.	

	PACE if he/she elects to obtain Medicare coverage other than from his or her PO.		
Other enrollment procedures (§460.156) (p. 84 and pp. 155-156)	CMS proposes to eliminate the requirement under §460.156(a)(4) for POs to give new PACE participants stickers for their Medicare and Medicaid cards, as applicable. Further, CMS proposes to revise requirements under §460.156(a)(2) to require that the PACE membership card indicates that he or she is a PACE participant and includes the phone number of the PO.	To ensure that participants' Medicare and Medicaid cards are not damaged if stickers are removed if a participant disenrolls, and to save participants from having to carry their Medicare and Medicaid cards with them.	Do POs anticipate any problems as a result of this change?
Voluntary disenrollment (§460.162) (pp. 84-85 and pp. 156-157)	CMS proposes to add §460.162(a) stating that a voluntary disenrollment is effective the first of the month following the date the PO receives the notice of voluntary disenrollment. CMS proposes to add §460.162(c) to "affirmatively require" that POs ensure their 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 a change in health status. CMS reiterates that this practice is subject to sanctions under §460.40(c).	Proposed requirement is consistent with current practice. CMS is including this new provision to prevent instances in which a participant needing additional services is encouraged to voluntarily disenroll by either an employee or contractor of the PO in an effort to reduce costs for the PO.	Do POs anticipate any problems as a result of this clarification?
Involuntary disenrollment (§460.164) (pp. 85-90 and pp. 157-158)	CMS proposes to add a new §460.164(a) specifying that a participant's disenrollment occurs after the PO meets applicable requirements, e.g., PO receives notice from SAA that PO has adequately documented acceptable grounds for disenrollment, and is effective on the first day of the next month that begins 30 days after the day the PO sends notice of the disenrollment to the participant. For example, if a PO send a disenrollment notice on April 5, the disenrollment would be effective June 1.	To clarify when a participant's involuntary disenrollment is effective and to protect participants' due process, as CMS' regulations and guidance do not currently include an advance notice requirement. CMS believes that 30 days would provide sufficient time for an individual to gather documentation, medical records, or other information in order to respond to the PO's proposed disenrollment action, should he or she disagree. Without the 30 days of advance notice, a PO could notify a participant about an involuntary disenrollment the first day of the following month, only a few days away. This would not allow sufficient time for a participant to contest the disenrollment or to effectively coordinate a transition to other care and services.	POs anticipate any problems as a result of this change?

	CMS proposes to revise redesignated §460.164(b) stating that POs may involuntarily disenroll a participant who fails to pay or fails to make satisfactory arrangements to pay any premium. In both cases, this can only be done after a 30-day grace period. The proposed revision would clarify that an involuntary disenrollment cannot be initiated due to a participant's failure to pay until after a 30-day grace period for the participant to pay or to make satisfactory arrangements to pay, e.g., a participant's agreement to pay through installments or to pay within a specific time period. CMS proposes to add two additional reasons for involuntary disenrollment: (1) after a 30-day grace period, failure to pay or failure to make satisfactory arrangements to pay any applicable Medicaid spenddown liability or any share of cost (due to post-eligibility treatment of incomes processes), and (2) situations where the participant's caregiver (including any family member involved in the participant's care) engages in disruptive or threatening behavior such that this behavior jeopardizes the participant's health or safety, or the safety of the caregiver or others. Disenrollment of a participant as a result of a disruptive/threatening caregiver may be pursued only after the PO has engaged in efforts to resolve the situation and has documented these efforts. Note: POs cannot disenroll a participant for a caregiver's noncompliance with the participant's plan of care or terms of the enrollment agreement.	To clarify that the 30-day grace period applies to both failure to pay and failure to make satisfactory arrangements to pay any premium due the PO. Adding these additional reasons for involuntary disenrollment means that waivers will no longer be required to allow for involuntary disenrollment due to non-payment of spenddown/share of cost, and disruptive or threatening behavior on the part of a participant's caregiver. Involuntary disenrollment would now be possible for nonpayment or failure to make satisfactory arrangements to pay both private-pay premiums and Medicaid spenddown/share of cost. The ability of POs to involuntarily disenroll participants for disruptive or threatening behavior on the part of caregivers recognize that it is not always possible for a PO to establish alternative arrangements that would not disrupt the PO's ability to provide adequate services in these situations.	
Effective date of disenrollment (§460.166) (p.90 and p. 158)	CMS proposes to change the title of §460.166 to "Disenrollment responsibilities."	This title will better reflect the focus of this section which is on the PO's responsibilities when disenrolling a participant, e.g., coordinate disenrollment date between Medicare and Medicaid, give reasonable advance to participant, continue to furnish services until date enrollment is terminated.	

Reinstatement in other Medicare and Medicaid programs (§460.168) (p. 91 and p. 158)	CMS proposes to specify that POs must make appropriate referrals and ensure medical records are made available to new providers within 30 days. "Within 30 days" replaces "in a timely manner."	To ensure that POs interpret "timely manner" uniformly and to help ensure that participants who disenroll from PACE experience a smooth transition to other Medicare and Medicaid programs. CMS believes that 30 days balances the need to give the PO adequate time to gather the medical records, make copies, and deliver them to new providers with the need to ensure that new providers receive the medical records as soon as possible to help ensure a smooth transition for the participant and continued access to medications and other needed ongoing care.	Based on POs' experience, is the 30-day timeframe reasonable and appropriate?
Subpart J – Payment (§460.182) (pp. 91-94 and p. 159)			
Medicaid payment (§460.182) (pp. 91-94 and p. 159)	Consistent with proposed revisions to §460.32(a)(12), CMS is proposing to revise §460.182(b) to require that the PACE program agreement contain the state's Medicaid capitation rate or the "methodology" for establishing the Medicaid capitation rates. CMS proposes to add a new §460.182(b)(3) which would require that the monthly capitation amount paid by the SAA be "sufficient and consistent with efficiency, economy, and quality of care."	Rationale consistent with rationale for proposed change to §460.32(a)(12) provided on p. 5. Currently, the regulation does not require that the Medicaid rate be adequate or sufficient to provide the services required under the PACE program for the enrolled population. Since the rate is only required to be less than what would have otherwise been paid by Medicaid outside of PACE, there is no lower bound for the rate. CMS is proposing new language to ensure that the Medicaid rate is sufficient for the population served under the PACE program, which CMS believes means not lower than an amount that would be reasonable and appropriate to enable the PO to cover the anticipated service utilization of the frail elderly participants enrolled in the program and adequate to meet PACE program requirements. In addition, CMS is proposing that the monthly capitation amount be consistent with efficiency, economy, and quality of care. By efficiency and economy, CMS means that the payment amount must reflect that POs bring more efficiencies to the administration, management and oversight of participant care because they are singularly	

	CMS is seeking comment on other rate methodologies CMS may consider requiring for Medicaid capitation payment amounts for PACE. CMS is seeking input on whether or not there could be other rate setting methodologies for PACE that are more consistent and competitive with rate setting methodologies used for other programs that provide similar services to similar populations on a capitated basis, e.g., actuarially sound rates required for financial alignment demonstrations. Comments are being requested to inform possible future rulemaking concerning Medicaid capitation payments.	responsible for all of a participant's care (including acute and long term care services), which in many cases outside of PACE are managed by multiple provider entities.	Should quality adjustments be used in Medicaid rate-setting for PACE? How would an actuarial soundness requirement impact rate-setting?
Subpart K – Federal/State Monitoring (§§460.190, 460.192, 460.194, 460.196) (pp. 94-99 and pp. 159-161)			
Monitoring during trial period (§460.190) (pp. 94-96 and pp. 159-160)	CMS is proposing changes that will allow CMS to undertake some of the activities listed in §460.190(b)(1)(i-iv) remotely and not as part of an onsite visit. To reflect this change in approach, CMS is proposing: (1) that the trial period review include an onsite visit to the PO which may include, but is not limited to, observation of program operations, and (2) a separate requirement in a new §460.190(b)(2) that the trial period review include a detailed analysis of the entity's substantial compliance with all significant requirements of sections 1894 and 1934 of the Social Security Act and PACE regulations, which may include review of marketing, participant services, enrollment and disenrollment, and grievances and appeals.	Rather than performing onsite all of the activities associated with monitoring during the trial period, CMS is proposing that some of these activities be performed using remote technologies, e.g., webinars, etc.	
Ongoing monitoring after the trial period (§460.192) (pp. 97-98 and p. 160)	CMS is proposing to delete language in §460.192(b) that requires onsite reviews every 2 years and replace it with the requirement that CMS, in cooperation with the SAA, will conduct reviews of the operations of POs as	CMS believes proposed change will balance its responsibilities of ensuring that all of the beneficiaries are receiving quality care with their duty to effectively manage their resources and ensure proper oversight. The proposed	

	appropriate, by utilizing a risk assessment as the means of selecting which POs will be audited each year. The risk assessment will rely largely on the organization's past performance, and ongoing compliance with CMS and state requirements, as well as other information that could indicate a PO needs to be reviewed, e.g., participant complaints or access to care concerns.	change mirrors CMS' approach in selecting organizations for audit in other programs such as MA and Part D.	
Corrective action (§460.194) (pp. 98-99 and p. 160)	CMS is proposing to clarify that POs must take action to correct deficiencies identified by CMS or the SAAs as a result of the following: (1) ongoing monitoring of the PO, (2) reviews and audits of the PO, (3) complaints from PACE participants or caregivers, and (4) any other instance CMS or the SAA identifies programmatic deficiencies requiring correction.	To clarify the circumstances which would require POs to take corrective action.	
Disclosure of review results (§460.196) (p.99 and p. 161)	CMS proposes to amend §460.196(d) to ensure that POs make results of CMS and SAA reviews available for examination not just by PACE participants, but by those individuals who may be making decisions about PACE participants' care, such as family members, caregivers and authorized representatives in order to make them fully aware of the PO's performance and compliance with requirements. CMS also encourages POs to make review results available to potential participants and the public, e.g., by releasing a summary of the reports online. Posting results online would satisfy requirements under proposed §460.196(d).	CMS' objective is to make not only participants, but others as well, fully aware of the PO's performance and compliance with requirements.	
Subpart L – Data Collection, Record Maintenance, and Reporting (§460.200) (p. 100 and p. 161)			
Maintenance of records and reporting of data (§460.200) (p. 100 and p. 161)	CMS proposes to modify record retention requirements from 6 to 10 years in §460.200(f)(1)(ii) and (iii) for participant health outcomes data, financial books and records, medical records and personnel records.	This change would make PACE record retention requirements consistent with MA, Part D and other requirements.	

Home and Community-Based Settings (HCBS) regulation at §441.301(c)(4):

(4) Home and Community-Based Settings. Home and community-based settings must have all of the following qualities, and such other qualities as the Secretary determines to be appropriate, based on the needs of the individual as indicated in their person-centered service plan:

(i) The setting is integrated in and supports full access of individuals receiving Medicaid HCBS to the greater community, including opportunities to seek employment and work in competitive integrated settings, engage in community life, control personal resources, and receive services in the community, to the same degree of access as individuals not receiving Medicaid HCBS.

(ii) The setting is selected by the individual from among setting options including non-disability specific settings and an option for a private unit in a residential setting. The setting options are identified and documented in the person-centered service plan and are based on the individual's needs, preferences, and, for residential settings, resources available for room and board.

(iii) Ensures an individual's rights of privacy, dignity and respect, and freedom from coercion and restraint.

(iv) Optimizes, but does not regiment, individual initiative, autonomy, and independence in making life choices, including but not limited to, daily activities, physical environment, and with whom to interact.

(v) Facilitates individual choice regarding services and supports, and who provides them.

(vi) In a provider-owned or controlled residential setting, in addition to the qualities at §441.301(c)(4)(i) through (v), the following additional conditions must be met:

(A) The unit or dwelling is a specific physical place that can be owned, rented, or occupied under a legally enforceable agreement by the individual receiving services, and the individual has, at a minimum, the same responsibilities and protections from eviction that tenants have under the landlord/tenant law of the State, county, city, or other designated entity. For settings in which the landlord tenant laws do not apply, the State must ensure that a lease, residency agreement or other form of written agreement will be in place for each HCBS participant, and that the document provides protections that address eviction processes and appeals comparable to those provided under the jurisdiction's landlord tenant law.

(B) Each individual has privacy in their sleeping or living unit;

(1) Units have entrance doors lockable by the individual, with only appropriate staff having keys to doors.

(2) Individuals sharing units have a choice of roommates in that setting.

(3) Individuals have the freedom to furnish and decorate their sleeping or living units within the lease or other agreement.

(C) Individuals have the freedom and support to control their own schedules and activities; and have access to food at any time.

(D) Individuals are able to have visitors of their choosing at any time.

(E) The setting is physically accessible to the individual.

(F) Any modification of the additional conditions, under 441.301(c)(4)(vi)(A) through (D), must be supported by a specific assessed need and justified in the person-centered service plan. The following requirements must be documented in the person-centered service plan:

(1) Identify a specific and individualized assessed need.

(2) Document the positive interventions and supports used prior to any modifications to the person-centered service plan.

(3) Document less intrusive methods of meeting the need that have been tried but did not work.

(4) Include a clear description of the condition that is directly proportionate to the specific assessed need.

(5) Include regular collection and review of data to measure the ongoing effectiveness of the modification.

(6) Include established time limits for periodic reviews to determine if the modification is still necessary or can be terminated.

(7) Include the informed consent of the individual.

(8) Include an assurance that interventions and supports will cause no harm to the individual.

(5) Settings that are not Home and Community-Based. Home and community-based settings do not include the following:

(i) A nursing facility;

(ii) An institution for mental diseases;

(iii) An intermediate care facility for individuals with intellectual disabilities;

(iv) A hospital; or

(v) Any other locations that have qualities of an institutional setting, as determined by the Secretary. Any setting that is located in a building that is also a publicly or privately operated facility that provides inpatient institutional treatment, or in a building on the grounds of, or immediately adjacent to, a public institution, or any other setting that has the effect of isolating individuals receiving Medicaid HCBS from the broader community of individuals not receiving Medicaid HCGS will be presumed to be a setting that has the qualities of an institution unless the Secretary determines through heightened scrutiny, based on information presented by the State or other parties, that the setting does not have the qualities of an institution and that the setting does have the qualities of home and community-based settings.