SECTION-BY-SECTION SUMMARY OF CHANGES TO PACE REGULATORY REQUIREMENTS IN PACE FINAL RULE
Prepared by National PACE Association, June 5, 2019

The information presented here summarizes changes to PACE regulatory requirements in 42 CFR Part 460 resulting from the Centers for Medicare & Medicaid Services' (CMS) publication of the PACE final rule in the Federal Register dated June 3, 2019. The new requirements are effective beginning August 2, 2019.[1] PACE organizations (POs) should take necessary steps between now and the effective date to ensure compliance, e.g., revise policies and procedures impacted by the final rule, undertake staff training, etc. Appendix A of this document is a "red-lined" version of the current rule identifying all the revisions/additions/deletions made by the June 3rd PACE final rule.

NPA is hopeful that this summary and the appendix will be helpful to its members in understanding the changes to PACE requirements effective August 2nd. In addition, we strongly encourage you to read the full text of the final rule as published in the Federal Register including the preamble which provides further explanation and rationale for the regulatory changes.

Page #[2]	Description of Changes to PACE Regulatory Requirements (42 CFR part 460) Resulting from PACE Final Rule	Additional Explanation of Changes/Suggested PO Actions in Response to Final Rule
GLOBAL CHANGE		
p. 25614; pp. 25672, 25673, 25675, 25676, 25677	All references to "quality assessment and performance improvement" in Part 460 are replaced with "quality improvement." Specific instances in which "quality assessment and performance improvement" has been replaced with "quality improvement" are not noted below.	"Quality improvement" is the reference more widely used by POs, State Administering Agencies (SAAs), the CMS, and the industry. Further, it is used to mean the same thing in other CMS programs and would allow for consistency in language across CMS programs.

[1] Because changes to existing PACE regulatory requirements take effect August 2, 2019, POs should not implement changes consistent with the new requirements until then.
[2] Version of final PACE rule published in Federal Register on June 3, 2019 (Vol. 84, No. 106, pp. 25610-25677) and available at https://www.govinfo.gov/content/pkg/FR-2019-06-03/pdf/2019-11087.pdf.

		POs should update written materials as needed with the updated term "quality improvement."
Subpart A – Basis, Scope, and Definitions		
p. 25614; p. 25671	Addition of new section ***§460.3 Part D Program Requirements*** to state that 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 42 CFR part 423.	Current PACE regulation makes no mention of Part D program requirements, so addition of §460.3 clarifies that POs must abide by applicable Part D requirements. This change clarifies existing policy and will not result in any change in the current treatment of POs offering Part D prescription drug coverage. No specific action is required of POs in response to this change.
Subpart B – PACE Organization Application and Waiver Process		
pp. 25614-25618; p. 25671	Several changes are made to ***§460.10 Purpose and §460.12 Application Requirements***, in large part to provide for POs' submission of service area expansion (SAE) applications. Consistent with the current PACE manual, three scenarios are identified under which a PO may expand operations: (1) it may expand its geographic service area without building additional sites; (2) it may open another physical site in the existing geographic service area; and (3) it may expand its geographic service area and open another physical site in the expanded area. The rule specifies that applications, both initial and SAE, must be submitted in the "form and manner specified by CMS" to allow for submission of applications and supporting information in forms other than paper. §460.12(b) now specifies that all applications, both initial and SAE, must be accompanied by an assurance from the SAA. The assurance accompanying an SAE application must indicate the State is willing to amend the PACE program agreement to include the new site and/or expand the PO's service area. Language in §460.22 is moved to §460.12(c) requiring that (1) an entity must describe the service area it proposes to serve in its application (initial application or SAE if application is proposing to expand its service area); and (2) CMS may, in consultation with the	Current PACE regulation refers only to applications from entities seeking to become POs; it does not address SAE applicants. The changes to §460.12 effectively codify in regulation the process that CMS has in place today for both initial and SAE applications. In its comments on the proposed rule, NPA had requested that CMS not require an SAE application from a PO seeking to add a new PACE center within an existing approved service area. Alternatively, NPA proposed a notice process. CMS did not accept this comment—a PO seeking to open a new center in its existing service area must continue to complete the SAE application process. On pp. 25617-25618 of the preamble, CMS speaks to circumstances that would allow a PO to relocate its PACE center prior to completion of the first trial period. While emergency or unforeseen circumstances may allow for this, CMS does not agree that relocation of a PACE center prior to completion of the first trail period audit should be allowed to assure adequate access if program growth exceeds enrollment projections. "A PO that intends to relocate its PACE center in order to satisfy increased enrollment demands would be required to wait until the first trial period audit is successfully completed."

	SAA, exclude an area already covered under another PACE program agreement. §460.22 has been deleted. §460.12(d) has been added to codify CMS' current practice of only approving SAE applications after a PO's successful completion of the first trial period audit and, if applicable, implementation of an acceptable corrective action plan.	These changes are consistent with current initial and SAE PACE application processes. No specific action is required of POs in response to these changes. Additional information on the PACE initial and SAE application is available at: https://www.cms.gov/Medicare/Health-Plans/PACE/Overview.html. For initial applicants, the PACE Part D application is available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2019-PACE-Part-D-Application.pdf.
p. 25618; pp. 25671-25672	In a minor change to ***§460.18 CMS Evaluation of Applications***, CMS clarifies that in addition to information included in the application itself, CMS can base its evaluation of initial or SAE applications on information obtained by CMS or the SAA through onsite visits as well as through other means, e.g, financial reviews, results from ongoing monitoring visits.	This change specifies in more detail the information that CMS can take into consideration in evaluating both initial and SAE applications. No specific action is required of POs in response to this change.
pp. 25618-25620; p. 25672	Changes to ***§460.20 Notice of CMS Determination*** specify requirements of CMS to notify SAE applicants of the status of their applications; previously only initial applicants were referenced in §460.20. §460.20 now codifies in regulation the notification timeframes in Chapter 17 of the PACE manual for SAE applications: 1) for SAE applications involving either a new center or an expanded geographic service area, CMS must approve the application, deny the application or request additional information within 45 days. If CMS requests additional information, CMS has 45 days following receipt of all the requested information to either approve or deny the SAE application. 2) for SAE applications involving both a new center and an expanded service area, as is the case with initial applications, CMS has 90 days to approve, deny or request additional information. If additional information is requested, CMS has 90 days following receipt of all the requested information to either approve or deny the SAE application.	

	In addition, new §460.20(c)(2), CMS states that 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 to the application. In the preamble to the rule (pp. 25619-25620) CMS clarifies that this would involve submitting all application-specific documentation that may have changed during the interim 12-month period. It is possible, depending on the nature of the changes and updates, there may be circumstances in which the applicant may be required to submit a completely new application, e.g., if there is a change in the legal entity that is applying to become a PO. In new §460.120(d), CMS clarifies that only initial applications will be deemed approved if CMS fails to act on the complete application within 90 days of its submission to CMS or within 90 days of the date CMS receives all requested additional information. Deemed approval does not apply to SAE applications.	In the proposed rule, CMS had proposed updates to applications would be required if more than 6 months elapse between the date of initial submission of the application and the entity's response to CMS' request for additional information. NPA recommended 12 months which was accepted by CMS. NPA had commented that SAE applications also be deemed approved if CMS were to fail to act within required timeframes, recognizing that this has not been the experience to date. CMS did not accept NPA's comment. No specific action is required of POs in response to these changes.
pp. 25620-25621; p. 25672	***§460.22 Service Area Designation*** has been deleted because its contents were moved to §460.12(c).	No specific action is required of POs in response to this change.
pp. 25621-25622; p. 25672	***§460.26 Submission and Evaluation of Waiver Requests*** has been modified to clarify requirements for submission of waiver requests, particularly those that accompany initial PACE applications. In all cases, regardless of whether the waiver is being submitted by a PO or an entity submitting a PACE application, the waiver request must initially be submitted to the SAA for initial review. For waivers that are being submitted to CMS outside of an application, the waiver should be forwarded to CMS by the SAA along with its concurrence, concerns or conditions regarding the waiver. If the waiver is being submitted by an entity that is submitting an initial application, the	The waiver submission process laid out in the regulation codifies CMS' current policy. The preamble (p. 25621) to the regulation suggests that waiver requests also can be submitted in conjunction with an SAE application although this is not mentioned specifically in the regulation. These changes are consistent with current policy regarding submission of waiver requests. No specific action is required of POs in response to this change.

	waiver request can be submitted separate from the application and should be forwarded to CMS by the SAA along with its concurrence, concerns or conditions. Alternatively, the waiver request can be submitted by the entity in conjunction with its application along with a letter from the SAA indicating its concurrence, concerns or conditions regarding the waiver request.	
pp. 25622-25623; p. 25672	Changes to ***§460.28 Notice of CMS Determination on Waiver Requests*** clarify that the 90-day clock for CMS' review of a waiver request begins upon CMS' receipt of a complete waiver request. Further, §460.28(a)(2) clarifies that a waiver request received from a PACE applicant, if approved, will be conditionally approved contingent upon approval of the application. In §460.28(d), CMS clarifies that CMS, in consultation with the SAA, may withdraw approval of a waiver for good cause and that notice of the withdrawal and its effective date must be provided to the PO or PACE applicant, and the SAA.	CMS suggests the requirement for waiver requests to be complete before the 90-day clock commences may result in fewer waiver denials. No specific action is required of POs in response to this change.
Subpart C – PACE Program Agreement		
pp. 25623-25625; p. 25672	***§460.32 Content and Terms of PACE Program Agreement*** specifies the required and optional content of a PACE program agreement. §460.32(a)(12) has been modified to allow for the program agreement to include either the Medicaid capitation rate(s) or Medicaid payment rate methodology.	This change is intended to address challenges that may result from requiring specific Medicaid payment amounts be included in the program agreement: 1) doing so may be challenging in states moving toward rate setting methodologies that result in numerous payment variations, perhaps even individual risk-adjusted rates; and 2) updating the program agreement to reflect annual changes in Medicaid capitation rates may be administratively challenging and/or burdensome. In its comments on the proposed PACE rule, NPA recommended that CMS modify the PACE regulation to allow for a prospective PACE organization to enter into a two-way agreement with CMS to provide services to Medicare beneficiaries in those states that do not elect PACE as a State option. CMS did not accept NPA's recommendation. No specific action is required of POs in response to this change.

Subpart D – Sanctions, Enforcement Actions, and Terminations		
p. 25625; 25672	Changes in ***§460.40 Violations for which CMS may Impose Sanctions*** allow for CMS to impose a sanction, i.e., suspension of enrollment or payment, or a civil money penalty, in situations where CMS makes a determination authorizing CMS to terminate a PO's program agreement under §460.50.	While this change expands the circumstances that could lead to a sanction, it also provides CMS an alternative to program termination in these situations. For example, sanctions may now be imposed if 1) there are significant deficiencies in the quality of care furnished to participants; or 2) the PO failed to comply substantially with conditions for a PACE program or the terms of its PACE program agreement, and the PO fails to develop and successfully implement a plan to correct the deficiencies. No specific action is required of POs in response to this change.
pp. 25625-25626; pp. 25672-25673	A change in ***§460.46 Civil Money Penalties*** clarifies that civil money penalty amounts will be adjusted annually for inflation.	No specific action is required of POs in response to this change.
Subpart E – PACE Administrative Requirements		
pp. 25626-25629; p. 25673	Several changes/clarifications are made in ***§460.60 PACE Organizational Structure***: (1) §460.60(a) has been deleted because the requirement that a PO be a not-for-profit entity no longer applies; (2) a PO planning a Change of Ownership (CHOW) must comply with all requirements in 42 CFR part 422, subpart L and must notify CMS and the SAA, in writing, at least 60 days before the anticipated effective date of the change; and (3) a PO planning a change in organizational structure, other than a CHOW, must notify CMS and the SAA, in writing, at least 14 days before the change takes effect. (Note: CMS considers a change in organizational structure to be one that may affect the philosophy, mission and operations of the PO.)	The changes in §460.60 are consistent with current policies. Although not mentioned in the regulation itself, the preamble reiterates CMS' requirement for an acquiring entity in a CHOW situation to become qualified as a PO if it is not already. This requirement means that acquiring entities that are not already qualified as POs must complete CMS' PACE application process as well as state-specific application processes. In response to an NPA comment, CMS indicates it would attempt to expedite a CHOW in a situation involving a PO that is seeking a CHOW due to financial hardship or other difficulties. No specific action is required of POs in response to this change.
p. 25629; p. 25673	A change in ***§460.62 Governing Body***, specifically to §460.62(a)(7) is intended to clarify that the governing body is ultimately responsible for ensuring the PO meets quality improvement program requirements in §460.130.	POs may need to modify documentation referencing the roles and responsibilities of their governing bodies consistent with this change.

pp. 25629-25632; p. 25673	A new ***§460.63 Compliance Oversight Requirements*** requires POs to implement a compliance oversight program that, at a minimum, establishes and implements 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. More specifically: (a) If the PO discovers evidence of misconduct related to payment or delivery of services, it must conduct a timely, reasonable inquiry into that conduct; (b) The PO must conduct appropriate corrective actions (e.g., repayment of overpayments, disciplinary actions against responsible employees) in response to the potential violation; and (c) The PO should have procedures to voluntarily self-report potential fraud or misconduct related to the PACE program to CMS and the SAA.	Although compliance program requirements in §423.504(b)(4)(vi)(F-G) of the Part D rule already apply to a PACE organization's Part D operations, up to this point, no specific compliance oversight requirements have been included in the PACE regulation. In the proposed PACE rule, CMS proposed that the two elements of a Part D compliance program required of POs in §423.504(b)(4)(vi)(F-G) for their Part D operations should be required of POs for their operations overall. In the final PACE rule, CMS chose to require just one of these elements (§423.504(b)(4)(vi)(G)) at this time due to concerns about potential burden. The addition of §460.63 to the PACE regulation will require POs to promptly respond to, investigate and correct potential non-compliance and fraud, waste and abuse. POs will need to create written training materials and written procedures for the expansion of their existing systems of responding to and correcting non-compliance to encompass all its operations, and to report potential fraud or misconduct. *Important Note: In addition to compliance requirements in the PACE and Part D rules, POs also are subject to compliance requirements under the Deficit Reduction Act, the Medicare repayment rule, federal sentencing guidelines, etc.*
p. 25632; p. 25673	The most significant change to ***§460.64 Personnel Qualifications for Staff with Direct Participant Contact*** is the modification of the requirement in §460.64(a)(3) for direct care staff to have one-year prior experience with a frail or elderly population. The revised requirement now calls for direct care staff to either have one year of experience working with a frail or elderly population or, in the absence of such experience, to receive appropriate training from the PO on working with a frail or elderly population upon hiring.	In the preamble to the rule, CMS explains that 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 direct care staff. If POs choose to hire staff that do not meet the one-year prior experience requirement, they will want to confirm that existing trainings and related materials are based on industry standards and provide individuals with the skills necessary to work with the frail or elderly population in PACE. In the preamble (p. 25632) CMS specifies that individuals, through training, "would be taught about the complexities and differences in geriatric patients,

	In addition, §460.64(a)(4) which requires direct care staff to meet a standardized set of competencies established by the PO before working independently no longer requires that these competencies be approved by CMS.	and that he or she needs to be gentler, more patient and more observant than with a healthy, younger population." Although CMS does not believe it is necessary for them to approve competency evaluation programs prior to their use, CMS emphasizes the expectation that the PO use current industry standards. No specific action is required of POs in response to this change.
pp. 25632-25633; p. 25673	Subsections (b) and (c) of ***§460.66 Training*** are moved to §460.71 Oversight of Direct Participant Care. (please see below)	No specific action is required of POs in response to this change.
pp. 25633-25634; p. 25673	Changes to ***§460.68 Program Integrity*** establish new prohibitions in §§460.68(a)(4) and (5) on employing individuals or contracting with organizations or individuals 1) 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 2) who have been convicted of specific crimes for any offense described in section 1128(a) of the Social Security Act. Rewording of §460.68(a)(3) provides POs some new discretion with respect to employing or contracting with individuals who have been convicted of criminal offenses related to physical, sexual, drug, or alcohol abuse or use. The PO now has more discretion to determine whether individuals with such convictions in their past pose a risk to the PO's participants.	CMS notes that these changes make PACE requirements more consistent with those applicable to long term care facilities. Further, in the preamble (p. 25633), CMS specifies that crimes in 1128(a) which now will exclude individuals from employment in PACE or from contracting with a PO include: (1) conviction of program-related crimes; (2) conviction related to patient abuse; (3) felony conviction related to health care fraud; or (4) felony conviction relating to controlled substance. 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. provide them with needed information consistent with these changes.
pp. 25634-25635; pp. 25673-25674	Changes to ***§460.70 Contracted Services*** highlight contracting requirements for an individual who is contracted by the PO to be a program director, medical director or to be part of the IDT. A new 460.70(d)(6)(i-iv) specifies that such contracts must require the individual to: (i) Perform all the duties related to its position as specified in this part (rule).	POs may need to modify policies and procedures referencing requirements of individuals contracted to be a program director, medical director or member of the IDT, and revise contractual agreements applicable to these positions consistent with these changes.

	(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.	In the preamble (p. 25635) CMS emphasizes the requirement in §460.70(a) that POs must have written contracts with each outside organization, agency, or individual that furnishes administrative or care-related services not furnished directly by the PO except for emergency services. CMS further clarifies that this requirement also applies to administrative or care-related services provided by a PO's parent organization. In the proposed PACE rule, CMS sought feedback on the applicability of the Home and Community-Based Settings (HCBS) rule to PACE. No changes to PACE requirements related to the HCBS Setting rule were made; CMS will be considering the feedback it received in future rulemaking.
pp. 25635-25636; p. 25674	Changes to ***§460.71 Oversight of Direct Participant Care*** are largely technical in nature. Language in §460.71(b)(4) is now consistent with language in §460.64(a)(5) requiring that all staff furnishing direct participant care services must be medically cleared for communicable diseases and have all immunizations up-to-date before engaging in direct participant contact. In addition, as noted above on p. 8, §§460.66(b) and (c) were moved to §§460.71(c) and (d) to consolidate related requirements regarding training of staff and competency evaluations for direct care staff in the same section.	No specific action is required of POs in response to this change.
pp. 25636-25638; p. 25674	Changes to ***§460.82 Marketing*** impact the definition of "principal languages of the community" and the scope of prohibited marketing practices. §460.82(c)(1) stipulates that POs must furnish printed marketing materials to prospective and current participants in English and in any other principal languages of the community. 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. This definition is consistent with	NPA had recommended that, in the absence of a state standard, a primary language in the community would be defined as any language spoken in the home by at least 10 percent of individuals who are eligible for PACE in the PACE organization's service area, i.e., individuals 55 years of age and older. CMS did not recognize this comment. POs which have no state standards for primary languages must determine which primary languages apply in their service areas and be able to furnish printed marketing materials to prospective

	requirements of Medicare Advantage organizations. CMS will be providing POs with a list of these languages. With regard to prohibited marketing practices: 1) CMS clarifies in §460.82(e)(3) that the prohibition on gifts or payments to induce enrollment does not include gifts of nominal value, as defined in CMS guidance, if they 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.	and current participants in these languages consistent with this change. This determination may involve consultation with CMS. 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 should confirm ongoing adherence with this requirement.
	2) CMS replaces language in §460.82(e)(4) to identify the following as a prohibited marketing practice: "Marketing by any individual or entity that is directly or indirectly compensated by the PO based on activities or outcomes unless the individual or entity has been appropriately trained on the PACE program requirements, including but not limited to, subparts G and I of this part." CMS goes further to remind POs that they are responsible for the activities of contracted individuals or entities—including agents or brokers—who market on their behalf and must document that training has been provided.	The training referenced in §460.82(e)(4) applies to all individuals or entities involved in marketing, both employed and contracted. Subpart G (Participant Rights) and Subpart I (Participant Enrollment and Disenrollment) are referenced specifically, but training must not be limited to these areas. Please note CMS' intent behind specifying that requirements for training apply to individuals or entities that undertake marketing activities that are directly or indirectly compensated by the PO based on activities or outcomes. Written this way, requirements for training do not apply to entities such as states, SHIP counselors, and advocacy groups which may engage in education about PACE but which are not directly or indirectly compensated by the PO. POs may now consider marketing activities that were previously prohibited since it has not been possible to contract outreach efforts to individuals/organizations whose sole responsibility involves direct contact with the elderly to solicit enrollment. POs must update/develop training materials to ensure compliance with this requirement for both employed and contracted

	3) In §460.82(e)(5), CMS elaborates on the prohibition on unsolicited direct contact to include not only door-to-door marketing but also "calling or emailing a potential or current participant without the individual initiating the contact." Lastly, the current requirement in §460.82(f) to maintain a documented marketing plan has been deleted.	marketing staff, as applicable, and develop policies and procedures to document training has been provided. CMS notes this prohibition is consistent with marketing requirements for MA organizations and Part D sponsors, and consistent with current PACE marketing guidance (https://www.npaonline.org/sites/default/files/Final%20PMG%20-%2010-2-2018.pdf). POs should confirm their marketing practices are consistent with this requirement. CMS explains that it determined this requirement was redundant and that CMS has access to pertinent information through other account management activities, e.g., through review of marketing materials and in meetings with POs. No specific action is required of POs in response to this change.
Subpart F – PACE Services		
pp. 25638-25639; p. 25674	A change in §***460.98 Service Delivery*** is made to §460.98(c)(1) to be consistent with changes in §460.102(c)(1) that expands the definition of primary care provider on the IDT to include a primary care physician, a community-based physician, a nurse practitioner or a physician assistant. As a result, the requirement in §460.98(c)(1) for primary care services furnished at each PACE center now includes services furnished by a primary care provider and nursing services and is no longer limited to physician and nursing services.	Please refer to §460.102 for requirements of POs related to changes in the definition of primary care providers in the final rule. Changes to §460.98 do not alter existing requirements of POs with respect to the settings where PACE participants receive care, specifically the PACE center and alternative care settings (ACSs). Comments from NPA to allow for greater flexibility in POs' use of the PACE center and ACSs are not reflected in the final rule but may be considered by CMS in future changes to PACE requirements. There is no timeframe for such changes.
pp. 25640-25643; p. 25674	Significant changes to ***§460.102 Interdisciplinary Team*** are intended to provide POs greater flexibility with respect to their use of these key staff. Specifically: 1) Changes to §460.102(b) allow for one individual to fill two separate roles on the IDT when the individual meets applicable state licensure requirements and is qualified to fill the two	It is important to note that 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

	roles and able to provide appropriate care to meet the needs of participants.	respect to how these roles are filled. References to the IDT imply involvement of all 11 roles inclusive of: primary care provider, RN, MSW, PT, OT, RT/activity coordinator, dietitian, home care coordinator, PACE center manager, personal care attendant or representative, and driver or representative. POs must consider how to effectively document that all 11 IDT roles are represented in situations where a single individual fulfills two roles on the IDT.
	2) Changes to §460.102(b)(1) allow for the role of the primary care provider on the IDT to be filled by a primary care provider as defined in §460.102(c) to be any one of the following: a) a primary care physician; b) a community-based physician; c) a physician assistant (PA); or d) a nurse practitioner (NP).	With this change, it will no longer be necessary for POs to have approved BIPA 903 waivers to use community-based physicians, nurse practitioners or physician assistants as primary care providers on the IDT. Note that the regulatory language specifically requires PAs and NPs to be State licensed and practicing within their scope of practice as defined by State laws with regard to oversight, practice authority and prescriptive authority. POs exercising this new flexibility will have to revise or develop policies and procedures for oversight of its primary care providers. POs with NP and/or community-based physician waivers may already have such P&Ps. POs must confirm that their use of NPs and PAs is consistent with all requirements in revised §460.102(c) and new §460.102(e) related to State laws with regard to oversight, practice authority and prescriptive authority.
	3) The requirement that IDT members "primarily serve" PACE participants eliminated and §460.102(d)(3) has been deleted.	By deleting the "primarily served" requirement, POs will have greater flexibility to employ part-time staff and utilize 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.
	The addition of a new §460.102(e) emphasizes that POs must ensure that all members of the IDT have appropriate licenses or certifications under State law, act within the scope of practice as	This change emphasizes current practice and requirements.

	defined by State laws and meet requirements of staff furnishing care directly to participants in §460.71.	
pp. 25643-25646; pp. 25674-25675	Changes to ***§460.104 Participant Assessment*** are numerous and include revisions to conform the rule to current policy as well as substantive changes allowing for more flexibility with respect to IDT members required to undertake scheduled and unscheduled assessments. **Initial Comprehensive Assessments** 1) Changes to §460.104(a)(1) specify that IDT members' initial assessments must be in-person and 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. 2) §460.104(a)(2) identifies the members of the IDT that must perform an initial assessment: primary care provider, RN, MSW, PT, OT, RT/activity coordinator, dietitian, home care coordinator. A change in §460.104(a)(2)(i) recognizes that the initial primary care assessment may now be performed by either a primary care physician, a community-based physician, an NP or a PA. 3) A change to §460.104(a)(3) specifies that the decision to include other professionals in the initial comprehensive assessment rests with the IDT vs. individual team members. 4) Changes to §460.104(a)(4) again emphasize that the initial comprehensive assessment must be in-person. The minimum elements of this assessment as specified in §460.104(a)(4)(i-xi) are not changed. 5) §460.104(b) specifies that, "Within 30 days of the date of enrollment, the IDT must consolidate discipline-specific assessments into a single plan of care for each participant through team discussions and consensus of the entire IDT." This establishes a specific timeframe for development of the initial plan of care as well as provides for more flexibility	POs must confirm that their policies and procedures for initial care plan development are consistent with the 30-day requirement. The final rule does not change the requirement for an initial in-person assessment by the primary care provider, RN, MSW, PT, OT, RT/activity coordinator, dietitian and home care coordinator. If necessary, POs should adjust their policies and procedures for initial assessments to reflect this change. In the preamble (p. 25643) CMS explains that the change in language from "discussion in team meetings" to the new "team discussions" is intended 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." For example, the

	regarding the format of IDT discussions, e.g., in-person meeting, teleconference or conference call.	format of the discussion may be video conferencing, conference call, or in-person meeting.
	6) A new §460.104(b)(1) establishes a new requirement that, if the IDT determines that certain services are not necessary to the care of a participant, the reasoning behind this determination must be documented in the participant's plan of care.	In the preamble (pp. 25643-25644), CMS explains that it expects the plan of care to reflect that the participant was assessed for all services even when a determination is made that certain services were unnecessary at that time. POs will need to modify their policies and procedure for care plan documentation to reflect this change. NPA will be seeking further clarification of CMS' expectations of POs in response to this requirement.
	Semiannual Reassessments §460.104(c) identifies the members of the IDT that must perform in-person semiannual reassessments at least once every six months: primary care provider (PCP), RN, MSW and other IDT members that the PCP, RN and MSW determine are actively involved in the development or implementation of the participant's care plan.	As a result of changes to §460.104(c) the RT/activity coordinator is no longer required to perform a semiannual reassessment unless he/she is determined by the PCP, RN and MSW to be actively involved in the development or implementation of the participant's care plan. Note that §460.104(c)(4) assigns the responsibility for determining which IDT members are actively involved in the development or implementation of the participant's care plan to the PCP, RN and MSW. POs must establish a process for making these determinations that ensures adequate documentation and is reflected in policies and procedures. Also, changes to §460.104(c) eliminate requirements for annual reassessments by the PT, OT, dietitian and home care coordinator. As is the case with the RT/activity coordinator, these disciplines must perform semiannual reassessments if they are determined to be actively involved in the development or implementation of the participant's plan of care as determined by the PCP, RN and MSW. *Note: The rule establishes minimum requirements for reassessments, e.g., a PO may decide that an annual rehab therapy assessment is necessary for all participants, including*

		situations in which neither a PT or OT is actively involved in the development or implementation of a participant's care plan.
	Unscheduled Reassessments due to Change in Participant Status §460.104(d)(1) identifies the members of the IDT that must perform an in-person unscheduled reassessment due to a change in participant status: primary care provider (PCP), RN, MSW and other IDT members that the PCP, RN and MSW determine are actively involved in the development or implementation of the participant's care plan.	The 2006 final regulation requires that an unscheduled reassessment due to change in status involves reassessments by eight IDT members (PCP, RN, MSW, PT, OT, RT/activity coordinator, dietitian, home care coordinator) so the changes in the final rule potentially reduce the numbers of IDT members required to perform assessments depending on who the PCP, RN and MSW determines is actively involved in the development or implementation of the participant's care plan. POs must establish a process for making these determinations that ensures adequate documentation and is reflected in policies and procedures.
	Unscheduled Reassessments due to Service Delivery Requests (SDRs) No changes were made to the requirements governing which IDT members must perform reassessments in response to SDRs. Appropriate members of the IDT, as identified by the IDT, must conduct a reassessment. For unscheduled reassessments due to service requests only, the final rule allows the IDT member(s) to conduct the reassessment via remote technology (e.g., telephone, video conferencing, live instant messaging or other media that allow sufficiently direct and interactive communication) in the following situations: 1) the IDT (on a case-by-case basis) determines the use of remote technology is appropriate; 2) the SDR will likely be approved; and 3) the participant/designated representative consent. However, an in-person reassessment must be conducted before an SDR can be denied.	Note that it is the PCP, RN and MSW who have the responsibility for identifying which members of the IDT must perform semiannual reassessments and unscheduled reassessments due to change in status. In contrast, for unscheduled reassessments in response to service requests, it is the IDT. In the preamble (pp. 25645-25646) to the final rule, CMS emphasizes that it expects IDT members to utilize their clinical judgement in determining when remote technologies are appropriate vs. when an unscheduled reassessment due to a service request should be conducted in-person. POs interested in pursuing the option for using remote technology for reassessments related to service requests must develop policies and procedures to do so. Such policies and procedures should ensure documentation of 1) the IDT's determination that use of remote technology is appropriate; and 2) the participant/designated representative's consent to use of remote technology.

pp. 25646-25647; p. 25675	Changes to ***§460.106 Plan of Care*** require the eight IDT members who performed initial in-person assessments to develop a comprehensive plan of care for each participant based on the initial comprehensive assessment findings. The preamble to the rule further explains that the care plan cannot be finalized without a team discussion and consensus involving the full 11-member IDT. The participant's initial care plan must be <u>finalized within 30 days of enrollment</u>. The final rule expands requirements for care plan content in §460.106(b). 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.	In response to comments, in the preamble to the final rule (p. 25647) CMS indicates that in rare cases there may be extenuating circumstances that prevent the IDT from finalizing a participant's initial care plan within 30 days of enrollment. In these rare situations, the PO is directed to document the specific circumstances and detail the steps taken to provide immediate care as needed and complete the assessment and plan of care as soon as feasible given the circumstances. Referring to new §460.104(b)(1) that establishes a new requirement that, if the IDT determines that certain services are not necessary to the care of a participant, the reasoning behind this determination must be documented in the participant's plan of care. POs must revise policies and procedures to reflect the new requirement to finalize participants' initial care plans within 30 days of enrollment and, as needed, to include additional requirements for care plan content including requirement to document the reasoning behind the IDT's determination that certain services are not necessary to the care of a participant.	
Subpart G – Participant Rights			
p. 25647; p. 25675	Changes to ***§460.112 Specific Rights to which a Participant is Entitled***, for the most part, simplify the regulatory language without changing it substantively. A change to §460.112(c)(3) specifies that a participant has the right to voluntarily disenroll at any time and such disenrollment is effective the first of the month following the date the PO receives the participant's notice of voluntary disenrollment. This language is identical to the change in §460.162 Voluntary Disenrollment.	CMS explains that a voluntary disenrollment is effective the first day of the month following the participant's notice because payments to POs is capitated and this effective date corresponds with the end of the capitated payment period. POs will need to evaluate their policies and procedures for consistency with the requirement to effectuate voluntary disenrollments the first of the month following receipt of the participant's notice of voluntary disenrollment and make modifications as necessary. Depending on their current voluntary disenrollment processes, POs may need to consult with their SAAs.	

pp. 25647-25648; p. 25675	Consistent with the change impacting marketing materials in §460.82(c)(1), the change to ***§460.116 Explanation of Rights*** stipulates that POs must write the participant rights in English and, in the absence of any state standards in any other principal languages of the community. §460.116(c)(1) defines such languages as any languages spoken in the home by at least 5 percent of the individuals in the PO's service area. §460.116(c)(2) clarifies that POs must display PACE participant rights in a prominent place in the PACE center.	POs which have no state standards for primary languages must determine which primary languages apply in their service areas and make the participant rights available in these languages consistent with this change to the final rule. This determination may involve consultation with CMS. This is not a new requirement but a change to specify that this section refers to PACE participant rights. POs must ensure that PACE participant rights are identified as such and prominently displayed in the PACE center.
Subpart H – Quality Improvement		
p. 25648; p. 25676	***§460.130 General Rule*** specifies the general rules for a PO's quality improvement program. The program must reflect the full range of services furnished by the PO, and a PO must take actions that result in improvement in its performance in all types of care. The final rule establishes a new general rule for quality improvement in §460.130(d), moving the requirement from §460.140 that POs must meet external quality assessment and reporting requirements, as specified by CMS or the SAA. As a consequence of this move, §460.140 is eliminated.	The change was made to consolidate the general requirements of POs' quality improvement program in the same section of the rule. No specific action is required of POs in response to this change.
pp. 25648-; p. 25676	Changes to ***§460.132 Quality Assessment and Performance Improvement Plan*** include replacing "quality assessment and performance improvement" with "quality improvement" throughout, specifying that the quality improvement plan must be "collaborative and interdisciplinary in nature."	The preamble provides an example of what CMS means by "collaborative and interdisciplinary:" A PO may identify as a goal the need to improve its organization's overall fall incident rate and develops a plan of action to address this need that involves soliciting recommendations concerning this issue from its staff and contracted resources (e.g., pharmacists, physicians, social workers, transportation providers and PTs). This plan of action is collaborative because it involves input from staff and IDT members with experience and knowledge, and it is interdisciplinary because those individuals have different skills, levels of education and professional backgrounds and different perspectives on how to improve the fall rate. It is assumed that

		POs already apply a collaborative, interdisciplinary approach to their quality improvement plans, so this change likely reflects current practice. POs should update their materials to specifically reference "collaborative and interdisciplinary" in the context of their written QI plans.
Subpart I – Participant Enrollment and Disenrollment		
p. 25649; p. 25676	The change to ***§460.150 Eligibility to Enroll in a PACE Program*** clarifies that the eligibility criteria used to determine whether an individual's health or safety would be jeopardized by living in a community setting must be established by the SAA.	This change reflects current practice. No specific action is required of POs in response to this change.
p. 25649; p. 25676	The change to ***§460.154 Enrollment Agreement*** further specifies in 460.150(i) that, "If a Medicaid-only or private pay PACE 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 from the participant's PO."	This change in the required contents for the enrollment agreement will require that POs update their enrollment agreements accordingly.
pp. 25649-25650; p. 25676	Changes to ***§460.156 Other Enrollment Procedures*** 1) eliminate the requirement in §460.156(a)(4) for a PO to give stickers to a newly enrolled participant for his/her Medicare and/or Medicaid card(s), as applicable; and 2) require that the membership card given by POs to a participant upon enrollment as per §460.156(a)(2) indicate he/she is a PACE participant and include the PO's phone number.	As of August 2, 2019, POs should no longer give a participant sticker(s) for his/her card(s); and POs' membership cards, if they do not already, must comply with new requirements to identify the holder as a PACE participant and include the PO's phone number.
pp. 25650-25651; p. 25676	***§460.162 Voluntary Disenrollment*** has been expanded to include two additional subsections: 1) Consistent with changes to §460.112(c)(3), §460.162(a) specifies that voluntary disenrollments take effect the first day of the month following the date the PO receives the participant's notice of voluntary disenrollment; and	The ability of a PACE participant to voluntarily disenroll without cause at any time is retained in §460.162(b). In the preamble (pp. 25650-25651), CMS emphasizes that delays in voluntary disenrollments beyond the first day of the following month due to states' Medicaid systems which may require notification in advance of a "cutoff date" are not acceptable. Depending on their current voluntary disenrollment processes, POs may need to modify their policies and procedures related to voluntary

		disenrollments consistent with the final rule, consulting with their SAAs as needed.
	2) New §460.162(c) requires 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."	POs must consider options for implementing this requirement, e.g., updates to training materials, contract addendums, etc., and put them into practice on or before August 2, 2019. In the preamble to the proposed rule (Federal Register, Vol. 81, No, 158, August 16, 2016, p. 54688) CMS states that this new requirement results from auditors identifying instances in which a participant needed additional services and was encouraged to voluntarily disenroll by a PO employee or contractor. Further, CMS reminds POs that such behavior is subject to sanctions under §460.40(c).
pp. 25651-25654; pp. 25676-25677	Changes to ***§460.164 Involuntary Disenrollment*** include: 1) New §460.164(a) specifies that an involuntary disenrollment: a) occurs after the PO notifies the SAA and the SAA has reviewed the involuntary disenrollment and determines the PO documented acceptable grounds for disenrollment; and b) 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.	An example of the new requirement for the effective date of involuntary disenrollment is as follows: Following the SAA's determination that the PO has acceptable grounds for disenrollment, if a PO sends a disenrollment notice to a participant on April 5, the disenrollment would be effective June 1. Thirty days after April 5 is May 5, and the first day of the next month after May 5 is June 1. CMS explains that this new requirement is intended to protect participants' due process. This requirement provides a participant a minimum 30 days (often significantly longer) 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.
	2) Clarification in new §460.164(b)(1) that a participant has a 30-day grace period during which he or she can pay or make satisfactory arrangements to pay a premium before the PO can pursue involuntary disenrollment.	Please note that a premium refers to a payment from a non-Medicaid participant, i.e., a participant with Medicare only, or neither Medicare nor Medicaid.
	3) Addition of two new reasons for involuntary disenrollment: a) new §460.164(b)(2) permits involuntary disenrollment if the participant, after a 30-day grace period, fails to pay or make	In the past, CMS has approved BIPA 903 waivers for these reasons for involuntary disenrollment; the final rule extends these reasons for involuntary disenrollment to all POs. As is the case with all

	satisfactory arrangements to pay any applicable Medicaid spend-down liability or any amount due under post-eligibility treatment of income processes as permitted under §460.182(c)(1) and §460.184; and b) in addition to permitting involuntary disenrollment of a participant for disruptive or threatening behavior, new §460.164(b)(3) also permits involuntary disenrollment in situations where a participant's caregiver, i.e., any family member involved in the participant's care, engages in disruptive or threatening behavior (defined in new §460.164(c)(2)) that jeopardizes the participant's health or safety, or the safety of the caregiver or others.	involuntary disenrollments, notice of involuntary disenrollment for these reasons 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. In the preamble (p. 25653) and in new §460.164(d), CMS emphasizes that a PO must only pursue involuntary disenrollment of a participant based on a caregiver's behavior after the PO has engaged in and documented efforts to resolve the situation. Further, CMS clarifies that a PO cannot involuntarily disenroll a participant based on the caregiver's noncompliance with the participant's plan of care or terms of the PACE enrollment agreement. Lastly, in the preamble (p. 25653), CMS specifies that the state must provide an appeal avenue for both Medicaid and non-Medicaid participants related to involuntary disenrollments. POs will need to modify their policies and procedures related to involuntary disenrollments consistent with the changes in the final rule. In addition, if necessary, POs may want to consult with their SAAs to ensure a common understanding of these requirements.
p. 25654; p. 25677	The only change to ***§460.166 Effective Date of Disenrollment*** is to change the section header to "Disenrollment responsibilities."	No specific action is required of POs in response to this change.
p. 25654; p. 25677	The change to ***§460.168 Reinstatement in other Medicare and Medicaid Programs*** specifies the timeframe—30 days—within which the PO must both make appropriate referrals and ensure medical records are made available to new providers in order to facilitate a participant's reinstatement in other Medicare and Medicaid programs after disenrollment.	POs will need to modify their policies and procedures consistent with this change.
Subpart J -- Payment		
pp. 25654-	Consistent with the change to §460.32(a)(12) (see page 5), ***§460.182 Medicaid Payment*** is revised to require the PACE Program Agreement to contain <u>either</u> the State's Medicaid	This change recognizes that it may be impractical to include capitation rates in the program agreement, e.g., if a State individually risk adjusts its capitation payments, and that updating

25656; p. 25677	capitation rates or the methodology used by the State to establish PACE Medicaid capitation rates.	the program agreement annually to reflect rate changes is operationally challenging and burdensome for POs, states and CMS. No specific action is required of POs in response to this change.
Subpart K – Federal/State Monitoring		
pp. 25656-25657; p. 25677	Changes to requirements for CMS and SAA monitoring of POs in ***§460.190 Monitoring During Trial Period*** revise regulatory requirements for trial period audits in §460.190 to make them more consistent with statutory requirements in Sections 1894 and 1934 of the Social Security Act (SSA) and to allow for CMS' greater use of technology to conduct oversight and monitoring activities remotely vs. on-site. A new §460.190(b)(2) includes in the scope of the audit a detailed analysis of the PO's substantial compliance with all significant statutory requirements of sections 1894 and 1934 of the SSA and regulation, which may include review of marketing, participant services, enrollment and disenrollment, and grievances and appeals. ***§460.192 Ongoing Monitoring After Trial Period*** is revised to eliminate the requirement for the CMS, in cooperation with the SAA, to conduct an on-site review of POs at least once every two years after POs' completion of the trial period. §460.192(b) now calls for CMS, in cooperation with the SAA, to conduct reviews of POs' operations as appropriate, as determined by a risk assessment of each PO which takes into account the PO's performance level and compliance with the significant requirements of Sections 1894 and 1934 of the SSA.	These changes do not substantively change the authority that CMS and the SAA have always had to conduct oversight on all significant statutory and regulatory requirements of POs. Further, with implementation of a new audit protocol in 2017 and since then, POs have already experienced greater use of remote technologies in their audits. In addition to aspects of the annual trial period audit that can be performed remotely, these audits will continue to include an on-site component which, at a minimum, will include observation of program operations. The preamble (p. 25657) elaborates that in performing a data-based risk assessment to determine the frequency of audits for a PO subsequent to its completion of the trial period, in addition to the PO's performance level and compliance with significant requirements of Sections 1894 and 1934, other factors such as participant complaints, access to care concerns, length of time between audits, self-reported adverse events, expansion activities, etc. may be taken into account. No specific action is required of POs in response to this change. Please note that as a consequence of this change it may no longer be the case that POs expecting to be audited in 2019 will be. Conversely, as has always been the case, it remains CMS' prerogative to audit more frequently than once every two years.

p. 25657; p. 25677	Additions to ***§460.194 Corrective Action*** clarify that POs must take action to correct deficiencies identified by the CMS or the SAA as a result of not only reviews and audits, but also ongoing monitoring of the PO, complaints from PACE participants and caregivers, and other instances in which the CMS or SAA identify programmatic deficiencies requiring correction.	No specific action is required of POs in response to this change.
pp. 25657-25660; p. 25677	A change to ***§460.196 Disclosure of Review Results*** requires a PO to make audit review results available in a place readily accessible to not only participants but also to other individuals who may make decisions about PACE participants' care, such as family members, caregivers and authorized representatives.	In the preamble (p. 25657), CMS encourages POs to make review results publicly available, e.g., by releasing a summary of the audit report online. In addition to expanding the range of potential recipients of the report, by posting results online the PO would satisfy requirements to make them accessible to participants' family members, caregivers and authorized representatives. POs will need to modify their policies and procedures consistent with this change.
Subpart L – Data Collection, Record Maintenance, and Reporting		
p. 25660; p. 25677	Changes ***to §460.200 Maintenance of Records and Reporting of Data*** stipulate that a PO 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; or (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 increased from 6 to 10 years.	In the preamble (p. 25660), CMS explains that the 10-year requirement makes PACE requirements consistent with the statute of limitations under the False Claims Act, and Medicare MA and Part D requirements. POs will need to modify their policies and procedures consistent with this change in the final rule.