**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Parts 423 and 460**

**[CMS–4168–F]**

**RIN 0938–AR60**

# Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE)

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Final rule.

**SUMMARY:** This final rule updates the requirements for the Programs of All-Inclusive Care for the Elderly (PACE) under the Medicare and Medicaid programs. The rule addresses application and waiver procedures, sanctions, enforcement actions and termination, administrative requirements, PACE services, participant rights, quality assessment and performance improvement, participant enrollment and disenrollment, payment, federal and state monitoring, data collection, record maintenance, and reporting. The changes will provide greater operational flexibility, remove redundancies and outdated information, and codify existing practice.

**DATES:** *Effective Date:* These regulations are effective on August 2, 2019.

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**SUPPLEMENTARY INFORMATION:**

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## I. Executive Summary

### *A. Purpose*

The purpose of this final rule is to revise and update the requirements for the Programs of All-Inclusive Care for the Elderly (PACE) under the Medicare and Medicaid programs. The rule addresses application and waiver procedures, sanctions, enforcement actions and termination, administrative requirements, PACE services, participant rights, quality assessment and performance improvement, participant enrollment and disenrollment, payment, federal and state monitoring, data collection, record maintenance, and reporting. The changes will provide greater operational flexibility, remove redundancies and outdated information, and codify existing practice.

### *B. Summary of Key Economic Provisions*

1. Compliance Oversight Requirements

Compliance programs, as found in the Medicare Advantage (MA) and Medicare Part D programs, have long been recognized as key to protecting against fraud, waste, and abuse. The importance of these programs has been highlighted by several of our oversight bodies. In the August 16, 2016 **Federal Register** (81 FR 54666), we published the proposed rule, entitled ''Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE).'' In that rule, as authorized by sections 1934(f)(3) and 1894(f)(3) of the Social Security Act (the Act), we proposed to adopt two key elements of the Part D compliance program in the PACE regulations. Specifically, we proposed to require each PACE organization (PO) to develop a compliance oversight program that will be responsible for monitoring and auditing its organization for compliance with our regulations. Additionally, we proposed to require POs to have measures that prevent, detect and correct non-compliance with CMS' program requirements, as well as measures that prevent, detect, and correct fraud, waste, and abuse. We received comments that indicated these requirements would potentially present a significant burden to POs and possibly take key staff away from providing participant care. After careful consideration of these concerns, and after re-analyzing the burden estimates, we are finalizing this provision in part.

2. Monitoring and Oversight of PACE Organizations

As a result of our experience with oversight and monitoring of the PACE program, we proposed flexibilities in connection with the current requirement that POs be monitored for compliance with the PACE program requirements during and after a 3-year trial period. We stated in the proposed rule that we must balance the responsibilities of ensuring that all of our beneficiaries are receiving quality care with our duty to effectively manage our resources and ensure proper oversight over all of the programs we manage. We proposed to use technology to enhance efficiencies in monitoring by remotely reviewing PO documents, which we have to date reviewed primarily through site visits. We also proposed to reduce the number of on-site visits after the 3-year trial period by utilizing a risk assessment to select which POs will be audited each year. We stated in the proposed rule that this risk assessment would rely primarily on an organization's past performance and ongoing compliance with CMS and state requirements. However, the risk assessment would also take into account other information that could indicate a PO needs to be reviewed, such as participant complaints or access to care concerns. We are finalizing the provisions related to federal and state monitoring as proposed.

3. Additional Flexibility for Interdisciplinary Team

This final rule makes several changes intended to expand the flexibilities of the interdisciplinary team (IDT) that comprehensively assesses and provides for the individual needs of each PACE participant. Key provisions in this final rule include permitting one individual to fill two separate roles on the IDT if the individual has the appropriate licenses and qualifications for both roles, and permitting the primary care provider that is required for each IDT to include nurse practitioners, physician assistants and community-based physicians, in addition to physicians. Another flexibility we are finalizing in this rule is removal of the requirement that members of the IDT must serve primarily PACE participants.

### *C. Summary of Costs and Benefits*

TABLE 1—SUMMARY OF COSTS AND BENEFITS

| Provision description | Total costs to POs | Total cost to government (without transfer) |
|---|---|---|
| Compliance Oversight Requirements. | This provision requires POs to create a compliance oversight program to allow prompt identification of non-compliance and report of fraud, waste and abuse. We estimate a one-time burden of $116,026.8 in the first year for developing the written materials and training necessary for the prompt identification and reporting of fraud, waste and abuse (124 PO × 15 hours per PO × 62.38 (hourly rate)). This cost when annualized over 3 years is $38,675.6. We further estimate an annual cost of $154,702 per year for POs reporting and responding to any suspected fraud, waste and abuse (124 PO × 20 hours per PO × $62.38 hourly rate). Thus, the total cost would be $38,675.6 initially and $154,702 afterwards. | The creation of this program does not have cost or savings to the government since it is the POs who are creating and using the compliance oversight program. |
| Monitoring | This provision reduces the required monitoring by CMS of POs. We estimate that there will be an annual savings to POs based on our proposal of $1,523,253. We expect 72 PO audits under the current regulations but only 35 audits as a result of this final rule. Consequently, the savings to PO would be the effort saved by not having to produce documentation and other administrative burdens that occur during an audit for 37 audits. Consequently, we are estimating the savings per audit for a PO to be approximately $41,169 (1 Nurse Manager at $53.69/hour × 2 (Factor for fringe benefits) × 150 hours per person plus 1 Executive Assistant at $28.56/hour × 2 (Factor for fringe benefits) × 150 hours per person) plus 1 Medical Record Technician at 20.59/hour × 2 (Factor for Fringe benefits) × 150 hours per person plus 1 Compliance Officer at 34.39/hour × 2 (Factor for Fringe benefits) × 150 hours per person). Therefore, the total savings to POs will be $41,169 × 37 = $1,523,253. | We estimate an annual savings of $2,638,144 to the government. We expect 72 PO audits under current regulations. We expect only 35 audits under this final rule. The savings to the government would be the effort saved by not having to perform 37 audits.<br>The cost per audit is 2 GS–13 × $1,980 travel + 200 hours for GS–13s × $46.46/hr GS–13 wage × 2 (Fringe benefit factor) + 60 hours for GS–15s × $64.59/hr GS–15 wage × 2 (Fringe benefit factor) + 20 hours for 1 GS–13 × 46.46/hr GS–13 wage × 2 (Fringe benefit factor) = $71,301.20. Hence, the total savings is $71,301.20 × 37 = 2,638,144.<br>The audit work includes all of the pre-audit work, including (i) compiling and (ii) submitting audit documentation; (iii) 2 weeks of audit fieldwork; the post-audit work of (iv) collecting and (v) submitting impact analyses, (vi) reviewing and (vii) commenting on the draft audit report, and (viii) submitting and (ix) implementing corrective action plans for conditions of non-compliance. |
| Additional Flexibility for the Inter-disciplinary Team (IDT). | This provision provides administrative flexibility for POs without compromising care by: (i) Permitting one individual to fill two separate roles on the IDT if the individual has the appropriate licenses and qualifications for both roles; (ii) permitting the primary care provider (required for each IDT) to include nurse practitioners, physician assistants and community-based physicians, in addition to physicians; and (iii) removing the requirement that members of the IDT must serve primarily PACE participants. While this provision provides greater flexibility in creating the IDT, it does not create cost or savings. | This provision has neither cost nor savings to the government due to the fact that many POs are currently exercising these flexibilities through PACE waivers. |
| Participant Assessments | The provision provides clarity on initial assessments, removes duplicative requirements for periodic reassessments, and provides greater flexibility for unscheduled reassessments. More specifically: The provision clarifies that: (i) Initial assessments must be done in-person and prior to completion of the plan of care (within 30 days); (ii) reassessments must be done semi-annually and requires a minimum of three IDT members; (iii) ''change in participant status'' reassessments require a minimum of three (instead of eight) IDT members; and (iv) remote technology may be used to conduct certain reassessments for participant requests that will likely be deemed necessary to improve or maintain the participants overall health status. The use of remote technologies to conduct these reassessments for participant requests under § 460.104(d)(2) results in savings from reduced travel costs for PO staff and PACE participants. We are scoring this as a qualitative savings since there are challenges with quantifying it. Similarly, the other provisions are qualitative savings to POs. | These provisions will not result in additional costs or savings to the government. |

TABLE 1—SUMMARY OF COSTS AND BENEFITS—Continued

| Provision description | Total costs to POs | Total cost to government (without transfer) |
|---|---|---|
| PACE Program Agreement—Include Medicaid Rate Methodology. | This provision provides states and POs the ability to adapt to potential payment rate changes and variations by allowing the inclusion of the Medicaid payment rate methodology in the PACE program agreement instead of the actual rates. Although this provision may reduce the burden of POs having to update agreements to include the actual Medicaid payment rates, this is not a mandatory requirement and we are not scoring this change since some states may elect to continue to include the Medicaid rates. | Since this is an option on the part of states, and some states may continue to elect to include the actual Medicaid rates in the program agreement, and because CMS will continue to review and approve state Medicaid PACE capitation rates, there is neither cost nor savings to the government. |
| Enforcement Actions | This provision allows CMS the discretion to take less punitive action, such as sanctions or CMPs, when authorized to terminate a PO. Because the provision authorizes lesser sanctions under the existing disciplinary process, the provision has neither cost nor savings to POs. | Because the provision authorizes lesser sanctions under the existing disciplinary process, the provision has neither cost nor savings to the government. |
| Application Process | This provision allows an electronic and automated PACE application and waiver process. Since this provision codifies existing practice it results in neither costs nor savings. | This provision codifies existing practice, and therefore, has neither cost nor savings to the government. |
| PACE Marketing | The provision strengthens beneficiary protections by prohibiting POs from: (i) Using agents/brokers that are not directly employed by the PO to market PACE programs, unless appropriately trained; (ii) unsolicited marketing by direct contact, including phone calls and emails. Since the purpose of prohibiting these marketing practices is to strengthen existing beneficiary protections, this provision is not considered a cost or savings. | This provision has neither cost nor savings to the government. |

## II. Background

### *A. Program Description*

The PACE program is a unique model of managed care service delivery for the frail elderly, most of whom are dually-eligible for Medicare and Medicaid benefits, and all of whom are assessed as being eligible for nursing home placement according to the Medicaid standards established by their respective states.

### *B. Legislative and Regulatory History*

1. Demonstration Project

Section 603(c) of the Social Security Amendments of 1983 (Pub. L. 98–21), as extended by section 9220 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) (Pub. L. 99–272), authorized the original demonstration PACE program for On Lok Senior Health Services (On Lok) in San Francisco, California. Section 9412(b) of the Omnibus Budget Reconciliation Act (OBRA) of 1986 (Pub. L. 99–509), authorized CMS to conduct a PACE demonstration program to determine whether the model of care developed by On Lok could be replicated across the country. The number of sites was originally limited to 10, but the OBRA of 1990 (Pub. L. 101–508) authorized an increase to 15 PACE demonstration programs. The PACE demonstration program was operated under a Protocol published by On Lok, Inc. as of April 14, 1995.

The PACE model of care includes, as core services, the provision of adult day health care and IDT care management, through which access to and allocation of all health services is managed. Physician, therapeutic, ancillary, and social support services are furnished in the participant's residence or on-site at a PACE center. Hospital, nursing home, home health, and other specialized services are generally furnished under contract. Financing of the PACE demonstration model was accomplished through prospective capitation payments under both Medicare and Medicaid. Under section 4118(g) of the OBRA of 1987 (Pub. L. 100–203), PACE demonstration programs had to assume full financial risk progressively over the initial 3 years. As such authority was removed by section 4803(b)(1)(B) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), PACE demonstration programs approved after August 5, 1997 had to assume full financial risk at start-up.

2. Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33)

Section 4801 of the BBA authorized coverage of PACE under the Medicare program by amending title XVIII of the Act to add section 1894 of the Act, which addresses Medicare payments and coverage of benefits under PACE. Section 4802 of the BBA authorized the establishment of PACE as a state option under Medicaid by amending title XIX of the Act and adding section 1934 of the Act, which directly parallels the provisions of section 1894 of the Act. Section 4803 of the BBA addresses implementation of PACE under both Medicare and Medicaid, the effective date, timely issuance of regulations, priority and special consideration in processing applications, and extension and transition for PACE demonstration project waivers.

As directed by section 4803 of the BBA, we published an interim final rule with comment period (IFC) on November 24, 1999, establishing requirements for PACE under sections 1894 and 1934 of the Act (64 FR 66234). The 1999 IFC was a comprehensive rule that addressed eligibility, administrative requirements, application procedures, services, payment, participant rights, and quality assurance under PACE.

3. The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554)

The following three sections of BIPA modified the PACE program:

- Section 901 extended the transition period for the PACE demonstration programs to allow an additional year for these organizations to transition to the permanent PACE program.
- Section 902 gave the Secretary of Health and Human Services (the Secretary) the authority to grandfather in the modifications these programs had implemented as of July 1, 2000. This provision allowed the PACE demonstration programs to continue

program modifications they had implemented and avoid disruptions in participant care where these modifications were determined to be consistent with the PACE model.

• Section 903 specifically addressed flexibility in exercising the waiver authority provided under sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act. It authorized the Secretary to modify or waive PACE regulatory provisions in a manner that responds promptly to the needs of PACE organizations (POs) relating to the areas of employment and the use of community-based primary care physicians. Section 903 of BIPA also established a 90-day review period for waiver requests. On October 1, 2002, we issued an IFC to implement section 903 of BIPA (67 FR 61496).

4. Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173)

On December 8, 2003, Congress enacted the MMA. Several sections of the MMA affected POs. Most notably, section 101 of the MMA affected the way in which POs are paid for providing certain outpatient prescription drugs to any Part D eligible participant. The MMA altered the payment structure for Part D drugs for POs by shifting the payer source for PACE enrollees who are full-benefit dual-eligible individuals from Medicaid to Medicare, and, in part, from the beneficiary to Medicare for individuals that are not full-benefit dual-eligible beneficiaries who elect to enroll in Part D. The MMA did not affect the manner in which POs are paid for the provision of outpatient prescription drugs to non-part D eligible PACE participants.

Section 101 of the MMA added section 1860D–21(f) of the Act, which provides that POs may elect to provide qualified prescription drug coverage to enrollees who are Part D eligible individuals. The MMA allows CMS the flexibility to deem POs as MA plans with prescription drug coverage (MA–PD) local plans and to treat POs that elect to provide qualified drug coverage in a manner similar to MA–PD local plans. Due to inconsistencies in the PACE and MMA statutes, we chose to treat POs in a similar manner as MA–PD plans, thereby avoiding conflicting requirements. The requirements that apply to POs that elect to provide qualified prescription drug coverage to Part D eligible enrollees are described in section II.T.3. of the January 2005 Part D final rule (70 FR 4426 through 4434).

In addition, section 236 of the MMA amended the Act to extend to POs the existing statutory Medicare and Medicaid balance billing protections that had previously applied to POs under the PACE demonstration program authority.

Section 301 of the MMA amended the Medicare Secondary Payer (MSP) provisions in section 1862(b) of the Act. These amendments clarify the obligations of primary plans and primary payers, the nature of the insurance arrangements subject to the MSP rules, the circumstances under which Medicare may make conditional payments, and the obligations of primary payers to reimburse Medicare. To implement section 301 of the MMA, we issued an IFC published in the February 24, 2006 **Federal Register** (71 FR 9466). The provisions in the IFC were finalized in a final rule published in the February 22, 2008 **Federal Register** (73 FR 9679). The IFC revised pertinent MSP regulations found at 42 CFR part 411. Our PACE regulations at § 460.180(d) specify that Medicare does not pay for PACE services to the extent that Medicare is not the primary payer under part 411. The MSP regulations found at 42 CFR part 411 set forth our current policies regarding MSP obligations involving other payers.

5. 2006 PACE Final Rule

On December 8, 2006, we issued a final rule (71 FR 71244) (hereinafter 2006 final rule) that finalized both the PACE IFC published in the November 24, 1999 **Federal Register** (64 FR 66234) and the PACE IFC published in the October 1, 2002 **Federal Register** (67 FR 61496).

For a complete history of the PACE program, please see the 2006 final rule (71 FR 71244 through 71248).

*C. PACE Regulatory Framework*

Sections 1894(f) and 1934(f) of the Act set forth the requirements for issuing regulations to carry out sections 1894 and 1934 of the Act. Sections 1894(f)(2) and 1934(f)(2) of the Act state that the Secretary must incorporate the requirements applied to PACE demonstration waiver programs under the PACE Protocol when issuing interim final or final regulations, to the extent consistent with the provisions of sections 1894 and 1934 of the Act. However, the Secretary may modify or waive these provisions under certain circumstances. Sections 1894(a)(6) and 1934(a)(6) of the Act define the PACE Protocol as the Protocol for PACE as published by On Lok, Inc., as of April 14, 1995, or any successor protocol that may be agreed upon between the Secretary and On Lok, Inc. We issued the 1999 and 2002 IFCs and the 2006 final rule under authority of sections 1894(f) and 1934(f) of the Act.

We believe sections 1894(f) and 1934(f) of the Act primarily apply to issuance of the initial interim and final PACE program regulations because they refer to the PACE Protocol,[1] which has now been replaced by the PACE program agreement.[2] Sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act permit the Secretary to modify or waive provisions of the PACE Protocol as long as any such modification or waiver is not inconsistent with and does not impair any of the essential elements, objectives, and requirements of the PACE Protocol and, in particular, does not modify or waive any of the following five provisions:

• The focus on frail elderly qualifying individuals who require the level of care provided in a nursing facility.

• The delivery of comprehensive integrated acute and long-term care services.

• The IDT approach to care management and service delivery.

• Capitated, integrated financing that allows the PO to pool payments received from public and private programs and individuals.

• The assumption by the PO of full financial risk.

While we believe sections 1894(f) and 1934(f) of the Act no longer have direct application to the PACE program in many respects, we believe the limitations on waivers and modifications continue to apply to updates to the PACE program to the extent the updates concern essential elements, objectives, and requirements of the PACE Protocol, as replaced by the PACE program agreement, or any of the five listed provisions.

## III. Summary of the Provisions of the Proposed Rule, and Analysis of Responses to Public Comments

In the August 16, 2016 proposed rule, we proposed to revise and update the policies finalized in the 2006 final rule to reflect subsequent changes in the practice of caring for the frail and elderly and changes in technology (for example, the use of electronic communications, including email, and the automation of certain processes) based on our experience implementing and overseeing the PACE program. We explained in the proposed rule that PACE has proven successful in keeping frail, older individuals, many of whom are eligible for both Medicare and

[1] *https://www.gpo.gov/fdsys/pkg/FR-1999-11-24/pdf/99-29706.pdf* (Addendum A).

[2] *https://www.cms.gov/Medicare/Health-Plans/pace/downloads/programagreement.pdf.*

Medicaid benefits (dual eligibles), in community settings.[3] However, it is necessary to revise some regulatory provisions to afford more flexibility to POs and state administering agencies (SAAs) as a means to encourage the expansion of the PACE program to more states, thus increasing access for participants, and to further enhance the program's effectiveness at providing care while reducing costs. Therefore, we proposed a number of flexibilities, including allowing non-physician medical providers practicing within the scope of their state licensure and clinical practice guidelines to serve in place of primary care physicians in some capacities, and permitting POs to better tailor the IDTs to improve efficiency, while continuing to meet the needs of their participants.

We received approximately 110 public comments on the proposed rule from POs, individuals, health care providers, advocacy groups, and states. In the sections that follow, we describe each proposed provision, summarize any public comments received on each provision, and provide our responses to the comments.

*A. Global Change Regarding Quality Assessment and Performance Improvement*

Part 460 encompasses the regulatory provisions pertaining to PACE. We proposed to replace all references to ''quality assessment and performance improvement'' in part 460 of the regulations (including subpart and section headings) with ''quality improvement.'' We noted in the proposed rule that we proposed this change because, in practice, the term ''quality improvement'' is used by the POs, SAAs, CMS, and the industry when referring to quality assessment and performance improvement for POs. Furthermore, the term ''quality improvement'' is used to mean the same thing in other CMS programs, such as the CMS Quality Improvement Organization Program and the MA Quality Improvement Program, so this change would allow for consistency in use of language across CMS programs. We stated that this would be a change in terminology only and would not designate a change in the requirements for the PACE quality program. As proposed, the change would affect the following sections and headings in the current regulations: §§ 460.32(a)(9), 460.60(c), 460.62(a)(7), 460.70(b)(1)(iii), 460.120(f), 460.122(i), 460.130(a), 460.132(a) and (c)(3), 460.134(a), 460.136(a), (b), (c), (c)(1) and (2), 460.138(b), and 460.172(c), and the headings of subpart H and §§ 460.132, 460.134, and 460.136. We noted in the proposed rule that, because we were proposing to remove § 460.140 in its entirety, we would not need to change the reference in that section.

As we received no comments on this global change, we are finalizing it as proposed.

*B. Subpart A—Basis, Scope, and Definitions*

1. Part D Program Requirements (§ 460.3)

In the 2006 final rule (71 FR 71248), we indicated that MA–PD requirements with respect to Part D prescription drug coverage would apply to POs that elect to provide qualified Part D prescription drug coverage. However, the PACE regulations make no mention of Part D program requirements. To clarify this policy, we proposed to add § 460.3, ''Part D Program Requirements,'' to state that the POs offering qualified prescription drug coverage and meeting the definition of a Part D plan sponsor (as defined at § 423.4) must abide by all applicable Part D program requirements in 42 CFR part 423. We explained in the proposed rule that when we issue Part D program guidance we often receive questions regarding applicability to PACE, and it has been our experience that POs are not always aware they must comply with Part D requirements unless a specific requirement has been waived. (For a list of the Part D regulatory requirements that are waived for POs, see section 2.4 of the Part D application for new POs, available at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ApplicationGuidance.html*.) We stated that we believed the proposed change is consistent with our current policy and does not involve any change in the current treatment of POs offering qualified Part D prescription drug coverage.

The following is a summary of the public comments we received on the proposed provision regarding Part D program requirements and our responses to comments.

*Comment:* Several commenters generally supported the proposal to include in the PACE regulations the requirement that POs offering Part D qualified prescription drug coverage comply with Part D program requirements in 42 CFR part 423. However, one commenter requested that the regulatory text include a list of Part D requirements that are waived for PACE and suggested that CMS issue Health Plan Management System (HPMS) guidance specifying which Part D requirements are applicable to PACE. The same commenter requested that CMS audits take into account differences between PACE and MA–PDs and Medicare prescription drug plans (PDPs). The commenter also requested that CMS help in reducing Part D premiums and other costs for PACE participants.

*Response:* Regarding the suggestion to list in the PACE regulations the specific Part D requirements that are waived for PACE, we prefer to maintain our current approach of listing the waived regulations in the Part D application for new POs, as well as the PACE program agreement. We believe our approach provides greater administrative flexibility (for example, to remove or add waived requirements) than if we codified the list in regulation. Further, we believe listing the waived regulations in the Part D PACE application is appropriate so that this information is readily available to all entities submitting an application. However, we agree that when we need to change how a waiver of Part D requirements is applied in PACE, or revoke a waiver based on new information or legal requirements, we should issue guidance to address those changes. For example, we will be issuing an HPMS memo to clarify the requirements for drug management programs in PACE to reflect the regulatory changes made in the final rule to implement the Comprehensive Addiction and Recovery Act (CARA) (83 FR 16440). Because the other comments concerning audits and assistance with reducing premiums and other costs address topics that were not covered in our proposal, we consider those comments to be outside the scope of this rule. We are finalizing the new § 460.3 as proposed, with one technical change to refer to the definition of a Part D sponsor ''in'' § 423.4 instead of ''at'' § 423.4.

*C. Subpart B—PACE Organization Application and Waiver Process*

1. Purpose (§ 460.10)

Section 460.10 describes the purpose of subpart B, which sets forth the processes for an entity to apply to become a PO and to apply for a waiver of certain regulatory requirements. We proposed to revise this section to add a new paragraph (a) to address the

[3] See the Medicare Payment Advisory Commission's June 2012 Report to the Congress, Medicare and the Health Care Delivery System, pp. 76–77, available at *http://www.medpac.gov/docs/default-source/reports/june-2016-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf*.

application process and a new paragraph (b) in which we proposed to move the current language in this section regarding the waiver process by which a PO may request a waiver of certain regulatory requirements. We also proposed to add § 460.10(a)(2) and (3) to describe the process for a PO to seek approval from CMS to expand an existing service area or add a new PACE center. We did not receive any comments on this proposal, and therefore, we are finalizing it as proposed.

2. Application Requirements (§ 460.12)

Section 460.12 sets forth the application requirements for an organization that wishes to participate in the PACE program. Section 460.12(a) currently requires an individual authorized to act for an entity to submit a complete application to CMS that describes how the entity meets all requirements in part 460 if the entity seeks approval from CMS to become a PO. As set forth in our PACE manual, an application must also be submitted for a PO that seeks to expand its service area and/or add a new PACE center site (see PACE Manual, Ch. 17, Sections 20.4 through 20.7). There are three scenarios specified in the PACE manual 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. Currently, POs are required to submit an application to CMS and the SAA to expand their geographic service area and/or add a new PACE center to their PO. In October 2004, we released the PACE expansion application, which was for existing POs that wish to expand their geographic service areas, and/or add a new PACE center to their PO.

As with initial applications, our guidance requires POs to submit an expansion application to CMS through the SAA. However, current regulations do not specify a process for POs to submit, and the SAA and CMS to approve, an expansion application. Therefore, we proposed to amend § 460.12(a) to specify that it also applies to expansion applications submitted by existing POs that seek to expand their service area and/or to add a PACE center site. Specifically, we proposed to add language in § 460.12(a) that an individual authorized to act for a PO that seeks to expand its service area and/or add a PACE center site must submit a complete application to CMS that describes how the PO meets all requirements in this part. We stated in the proposed rule that we believed including this requirement in § 460.12 will help ensure POs understand our current practice of requiring an expansion application for a PO that seeks to expand its service area and/or add a PACE center site.

We also proposed to add the phrase ''in the form and manner specified by CMS'' to § 460.12(a) 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, to allow for submission of applications and supporting information in formats other than paper, which was the required format at the time the proposed rule was issued. As we explained in the proposed rule, paper applications were often hundreds of pages long, expensive to reproduce and transmit, and administratively inefficient, as staff reviewing different parts of the application are located in different physical locations and must receive hard copies of the material. We noted that to adapt to the increased use of electronic communications, electronic health records, and electronic data storage and exchange, we must continuously update the form and manner by which we administer our programs. We stated that we had successfully transitioned the MA application and PDP application to a fully electronic submission process, enabling a more organized and streamlined review, and wanted to bring those same efficiencies to the PACE application process. We also noted that we will provide further guidance on this process through HPMS or similar electronic system that may replace HPMS. Effective March 31, 2017, the first quarterly application submission date, we required POs to submit all applications electronically via HPMS, including initial applications, and applications for existing POs to expand their service area and/or add a PACE center site. POs and applicants may also refer to the CMS online tools for application submission at *https://www.cms.gov/Medicare/Health-Plans/PACE/Overview.html*.

Section 460.12(a)(2) provides that we would accept applications from entities that seek approval as POs beginning on February 22, 2000, except we would accept applications on earlier dates for certain entities that qualify for priority processing or special consideration. We established this provision and two other sections of the PACE regulations, previously found at § 460.14 and § 460.16, to implement section 4803(c) of the BBA of 1997. Section 4803(c) directed us to give priority in processing applications, during the 3-year period following enactment of the BBA of 1997, to PACE demonstration programs and then to entities that had applied to operate a PACE demonstration program as of May 1, 1997. In addition, section 4803(c) of the BBA of 1997 required that we give special consideration in the processing of applications during the 3 years following enactment to any entity that as of May 1, 1997, had indicated specific intent to become a PO through formal activities such as entering into contracts for feasibility studies. In the 2006 final rule (71 FR 71253), we deleted § 460.14 (Priority Consideration) and § 460.16 (Special Consideration) because the authority to provide these considerations expired on August 5, 2000. For the same reason, in the proposed rule, we proposed to delete paragraph (a)(2) of § 460.12, as it is no longer applicable.

Section 460.12(b) provides that an entity's application must be accompanied by an assurance from the SAA of the state in which the program is located indicating that the state (1) considers the entity to be qualified to be a PO and (2) is willing to enter into a PACE program agreement with the entity. However, we have received applications without the required SAA assurance. To help ensure that our current policy is clear, we proposed to revise the language to require that the entity's application to become a PO include an assurance from the SAA that the state considers the entity to be qualified to be a PO and the state is willing to enter into a PACE program agreement with the entity. We explained in the proposed rule that we want entities to understand we would not consider an application to become a PO to be complete without assurance from the SAA that the state both considers the entity to be qualified to be a PO and is willing to enter into a PACE program agreement with the entity. We noted that we would not review applications that do not include this assurance.

Similarly, we proposed to redesignate paragraphs (b)(1) and (2) as § 460.12(b)(1) and add a new paragraph (b)(2) to codify the current requirement in the PACE expansion application that a PO's application to expand its service area and/or add a new PACE center site must include an assurance from the SAA that the state is willing to amend the PACE program agreement to include the new PACE center sites and/or expand the PO's service area. We noted that we also expect, as we stated in the preamble to the 1999 IFC for initial applications (64 FR 66238), that the SAA will verify that an applying entity has qualified administrative and clinical

staff employed or under contract prior to furnishing services to participants in the expanded service area.

In addition, we proposed to move the language in § 460.22, which requires an entity to state in its application the service area it proposes for its program, and provides that CMS (in consultation with the SAA) may exclude an area already covered under another PACE program agreement, to proposed paragraph § 460.12(c) and remove § 460.22. As proposed, § 460.12(c)(1) would specify that both an entity submitting an application to become a PO and a PO submitting an application seeking to expand its service area must describe the proposed service area in their application. We also proposed to make a corresponding change to the Medicare Part D definition of ''Service area'' in § 423.4 for PACE plans offering qualified prescription drug coverage by removing the reference to ''§ 460.22 of this chapter'' and adding in its place ''§ 460.12(c) of this chapter,'' as our proposed changes would move the language currently in § 460.22 to § 460.12(c).

Finally, to codify CMS' current practice regarding the permissibility of POs to expand their service area and/or add a new PACE center site (see PACE Manual, Ch. 17, Section 20.4), we proposed to add § 460.12(d), which would provide that CMS and the SAA will only approve an expansion application after the PO has successfully completed its first trial period audit and, if applicable, has implemented an acceptable corrective action plan.[4]

We stated in the proposed rule that we believed all of these changes to § 460.12 would streamline the regulations and make the requirements clear and consistent with the PACE statutes. We noted that we will provide subregulatory guidance on application submission requirements after publication of the final rule.

A discussion of the comments we received on the proposed changes to the application requirements, and our responses to those comments, appears below.

*Comment:* One commenter questioned how the state will ensure that the required state assurance that is to accompany an initial or expansion application is accurate without additional monitoring. The commenter also questioned if the state will be required to perform additional monitoring (with supporting documentation) to prove that an expanding PO is indeed qualified to expand its service area or add an additional PACE center.

*Response:* The PACE regulations currently require that an entity's application to become a new PO be accompanied by an assurance from the SAA that the state considers the entity to be qualified to be a PO and is willing to enter into a PACE program agreement with the entity. In proposing to revise § 460.12(b), we sought to clarify in the regulations that, similar to the requirement for an initial application, the SAA must provide an assurance to us that the state is willing to expand the existing PACE program agreement to add to an existing service area and/or add a new PACE center. Given that we, in cooperation with the SAA, already conducts ongoing monitoring of a PO, we expect the state will determine what if any additional information is needed from a PO before providing the required assurance. As required by Chapter 17 of the PACE manual (Sections 10, 20.6, 20.7 and 30.2), if the PO is seeking to expand by adding a new PACE center, the SAA is responsible for conducting the state readiness review (SRR) of the PACE center to ensure that it meets the regulatory requirements for environment and staffing, and must provide the results to us before the expansion application can be approved.

*Comment:* Some commenters expressed support for CMS' proposal to modernize the application process for entities that seek to become new POs or to expand existing service areas or add new PACE center sites, acknowledging that the electronic exchange of information will expedite the processing of applications and be less burdensome for both POs and CMS.

*Response:* We thank the commenters for their support.

*Comment:* A variety of commenters, including PACE associations, supported the proposed requirements related to the submission of initial applications by entities seeking to become POs, as well as applications submitted by POs to expand their geographic service areas. Commenters recommended that CMS not require a PO to submit a formal expansion application in order to add a new PACE center within an existing service area. Commenters suggested that instead of requiring an expansion application for a new PACE center, CMS only require a PO to provide advance notification (a minimum of 60 days in advance) at any time (not limited to the quarterly application submission cycle), and report specific information (for example, location of the new PACE center, SAA assurance of support, willingness to amend the PACE program agreement, attestation of financial solvency with supporting documentation as evidence of the program's financial capacity, etc.), along with a completed SRR prior to the opening of the new PACE center. Commenters suggested that subsequently, but still prior to the new PACE center's opening, the PO would submit any revised marketing materials to CMS for review. Some commenters also suggested that a similar process, with no expansion application requirement, would be sufficient for circumstances in which a PO is simply moving a PACE center to a new location and relocating the IDT. Other commenters noted that removing the current requirement to submit applications on a quarterly cycle would enable POs to open a new PACE center more quickly to build capacity in response to increasing enrollment.

*Response:* We do not agree with the suggestion to remove the expansion application requirement for existing POs seeking to add a new PACE center within an existing service area for a number of reasons. First, the submission of an expansion application in which the PO seeks to add a new PACE center in an existing service area ensures that a structured, formalized process is employed consistently, regardless of expansion type, and ensures that the PO is providing proper assurances that PACE requirements are being met and that appropriate documentation is provided and included as part of the PACE program agreement. Furthermore, an expansion application requirement benefits both CMS and the PO, as both parties are held accountable and are required to adhere to established timeframes and deadlines. Perhaps most importantly, the submission of a formal expansion application, regardless of type, enables us to make a determination based on a standardized mechanism and affords the PO the opportunity to request reconsideration of denials by us. Regarding commenters' suggestion that a similar alternative process, with no expansion application requirement, could also be employed when a PO is simply moving a PACE center to a new location and relocating the IDT, we would point to our guidance that addresses expectations of POs under these circumstances. (See the October 21, 2016 HPMS memorandum, PACE Replacement Center Transition Guidance.) POs that seek to relocate an existing PACE center should follow this subregulatory guidance.

*Comment:* A commenter suggested that the SRR be appropriately tailored to situations in which a PO is applying to

[4] The PACE manual is available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs-Items/CMS019036.html.*

either expand its service area or add a new PACE center site, stating that the SRR in these instances should not be the equivalent to an SRR conducted for and included in an initial application.

*Response:* We note that an SRR is not required for service area expansion (SAE) applications that do not include the addition of a new PACE center. We recognize that the SRR is typically the primary driver of delay in final approval when a PO applies for an expansion that includes the addition of a new PACE center site. However, the SRR is also a critical component of an expansion application that includes a new PACE center, as it assures that all state-based licensure requirements are met and building and safety codes are satisfied. The SRR primarily consists of reviewing requirements specific to the PACE center itself, such as construction, equipment and maintenance to assure physical safety of participants and personnel. While there are some SRR requirements that may remain the same as the existing PACE center(s), such as transportation, contracts and policies and procedures, that may not be the case if the new PACE center is geographically distant from the existing PACE center. For example, there may be a different transportation provider or other new contractors that are more accessible to the new PACE center location. Because of those variables, we believe it would be difficult to tailor the current SRR for an expansion application that includes addition of a new PACE center.

*Comment:* Some commenters requested that CMS specify in § 460.12 that an expansion application will not have to include information previously submitted to CMS as part of the initial application. Another commenter noted that streamlining the administrative process removes a burden for both POs and CMS in processing these applications.

*Response:* While SAE applicants were previously required to submit a smaller subset of documents than initial PACE applicants, in March 2018, as part of the first quarterly application submission cycle, CMS began requiring SAE applicants to respond to the same attestations and upload the same documentation as initial PACE applicants. The PACE program agreement is the binding document between the PO, CMS and the SAA. We have found that program agreements, particularly for POs that have been active for some time, may not fully represent current operational policies and procedures and other information that is required content of the program agreement under § 460.32. We understand commenters' concerns regarding the potential burden associated with SAE applicants having to upload documents previously submitted as part of an initial application. However, in addition to providing added assurance and evidence that an active PO is qualified to expand its PACE program, we believe the application process is an appropriate, efficient and effective vehicle for capturing documentation that is required as part of the PO's PACE program agreement, including changes to operational policies and procedures, and eliminates the need to require the PO to submit additional information separately. While not explicitly addressed in this rule, we note that comments received from the PACE industry in response to an information collection request (CMS–10631, OMB 0938–1326) regarding this approach for SAE applications have generally indicated support for requesting information as part of the SAE application itself in order to facilitate efforts to update the PACE program agreement. This information collection request is subject to renewal and expires on December 31, 2021.

We believe this approach results in a more streamlined process and reduced burden for all parties to the PACE program agreement.

*Comment:* Commenters expressed support for the proposed provision in § 460.12(d), which would require a PO to have completed its first trial period audit and, if applicable, implemented an acceptable corrective action plan before CMS and the SAA will approve a service area expansion or PACE center expansion, with two specific modifications. Commenters requested an exception to this requirement when the PO is relocating its PACE center to a new location due to unforeseen circumstances or to assure adequate access if program growth exceeds enrollment projections. In addition, because the timing of the first trial period audit affects the ability of a PO to grow, commenters requested that CMS and the SAA commit to conducting trial period audits in a timely manner, with an expectation that the first year audit be completed no later than 15 months after the opening of the PACE program.

*Response:* We appreciate the support for the proposed provision in § 460.12(d) and acknowledge that unforeseen or otherwise exceptional circumstances, such as storm damage from a hurricane, may require a PO to immediately relocate its PACE center prior to completion of the first trial period audit. In situations that constitute emergency events, we would expect the PO to implement its emergency preparedness plan under § 460.84, which should include established plans and procedures for continued care of all participants, including those who had previously required regular PACE center attendance, as well as those who predominantly or exclusively receive care at home or in alternative care settings, as applicable. In the event such emergency circumstances require the relocation of a PACE center, either on a temporary or permanent basis, we would work with the PO and the SAA to ensure that the PO's emergency preparedness plan is implemented effectively and in a manner that maintains the health and safety of participants and staff. Such circumstances vary widely and present unique challenges; and we will expect the PO, to the extent possible, to address the items identified in the transition plan included as part of the October 21, 2016 HPMS memorandum, PACE Replacement Center Transition Plan guidance, while recognizing that the guidance may need to be tailored in response to the emergency situation presented. The priority under such circumstances will be to ensure that participants continue to receive necessary medical care and IDT members are able to continue to function and serve the needs of participants in a safe environment, regardless of setting. We would not require submission of an expansion application in this type of emergency situation, and do not believe it is necessary to amend § 460.12(d) to address unforeseen or otherwise exceptional circumstances.

We also do not agree that an exception should be made to allow relocation of a PACE center prior to completion of the first trial period audit in order 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. We believe this is reasonable because it enables us to ensure the PO is satisfying all requirements of the PACE program within the initial enrollment capacity constraints prior to accommodating increased enrollment. We also appreciate the comment regarding the timing of the first review during the trial period. We are committed to conducting timely annual reviews during each contract year of the PO's trial period. We will continue to

schedule reviews as expeditiously as possible consistent with statutory and regulatory requirements for the PACE program.

After considering the comments, we are finalizing the changes to § 460.12 as proposed.

3. CMS Evaluation of Applications (§ 460.18)

Section 460.18 describes the information that CMS uses to evaluate an application under PACE; however, this does not take into account all the potential sources of information that may be a part of the evaluation process, including information used in the evaluation of applications submitted for a PO that seeks to expand its service area and/or add a new PACE center site. Currently, § 460.18(b) specifies that CMS will use information obtained through on-site visits conducted by CMS or the SAA. Section 460.18(c) provides that CMS will use information obtained by the SAA. As discussed earlier in this section, we proposed to revise our regulations to reflect that an application also must be submitted for a PO that seeks to expand its service area and/or add a new PACE center site. We explained in the proposed rule that in evaluating expansion applications, CMS may consider additional information beyond that contained in the application itself, information obtained through on-site visits, or information obtained through the SAA. For example, our review of a SAE application might include information obtained from financial reviews, as well as the results from ongoing monitoring visits. Therefore, we proposed to combine the language currently in § 460.18(b) and (c) in revised § 460.18(b) and delete § 460.18(c). The revised § 460.18(b) would state that CMS uses information obtained by CMS or the SAA through on-site visits or any other means. We noted that this change would take into account the additional information that we use to review any PACE application, including applications to expand a PO's service area or add a new PACE center site. We also proposed to make a conforming change to the introductory language in § 460.18 to reflect the review of expansion applications, by deleting ''for approval as a PACE organization.''

A discussion of the comments we received on the proposed changes to the application evaluation requirements, and our responses to those comments, appears below.

*Comment:* One commenter noted the proposed modification would enable CMS to use information obtained by CMS or the SAA through on-site visits or any other means in order to evaluate a PACE application, and requested clarification regarding what encompasses ''any other means.''

*Response:* As we stated in the proposed rule (81 FR 54671), it is our intent to capture all the potential sources of information that may be part of the application evaluation process. Information obtained by ''any other means'' may include, but is not limited to, information obtained through the SAA, from financial reviews, or from ongoing monitoring visits.

We are finalizing the modifications to § 460.18 as proposed.

4. Notice of CMS Determination (§ 460.20)

Section 460.20 describes requirements for CMS to notify PACE applicants of the status of PACE applications. Currently, § 460.20 only specifies the requirements for CMS determination of applications submitted by entities seeking to become POs. As previously discussed in this section, we proposed to amend the regulations in subpart B to include, in addition to requirements for applications from entities seeking to become POs, requirements for applications submitted by existing POs for service area and/or PACE center site expansions. In conjunction with that proposal, we proposed changes to § 460.20 to also include specific language regarding the notification requirements for CMS determination of applications to expand a PO's service area and/or to add a new PACE center.

As we explained in the proposed rule, the current requirements in § 460.20 implement sections 1894(e)(8) and 1934(e)(8) of the Act, which require that an application for PO status be deemed approved unless the Secretary, within 90 days after the date of the submission of the application to the Secretary, either denies such request in writing or informs the applicant in writing with respect to any additional information that is needed in order to make a final determination with respect to the application. The Act further states that, after the date of receipt of any additional requested information from the applicant, the application must be deemed approved unless the Secretary, within 90 days of such date, denies such request.

While the Act requires that CMS provide notice to entities seeking to become POs of its determination within 90 days, the Act does not set out requirements for applications submitted by existing POs to expand their service area and/or to add a new PACE center site. We have published expansion application requirements in Chapter 17 of the PACE manual, available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019036.html.* Under that guidance, a PO is required to submit an expansion application when the PO is seeking to (1) expand its geographic service area; (2) add a new PACE center; or (3) expand its geographic service area and add a new PACE center.

The guidance provides that, when a PO submits an expansion application to expand its geographical service area without building additional sites, CMS has 45 days to request additional information from the PO, approve the application, or deny the application. Similarly, when a PO submits an expansion application to add a new PACE center in the existing service area, CMS has 45 days to request additional information from the PO, approve the application, or deny the application. In these scenarios, if CMS requests additional information and the applicant provides the requested information, CMS has an additional 45 days to review and either approve or deny the expansion application. The second 45-day review period in this scenario only commences once CMS has received all of the additional requested material. If the applicant submits additional information per CMS' request, but CMS determines that there is still outstanding information requested from the applicant, CMS notifies the applicant and the additional 45-day review period does not begin until all requested information is received. Once we have received all of the requested information, CMS sends a letter to the applicant indicating that the second 45-day review period has commenced.

In the third scenario, when a PO submits an expansion application to expand its geographic service area and open a new PACE center site, CMS has 90 days to request additional information from the PO, approve the application, or deny the application. In this scenario, if CMS requests additional information and the PO provides the requested information, CMS has an additional 90 days to review and either approve or deny the expansion application. The second 90-day review period in this scenario only commences once CMS has received all of the additional requested material. If the applicant submits additional information per CMS' request, but CMS determines that there is still outstanding information requested from the applicant, CMS notifies the applicant and the additional 90-day review period does not begin until all requested

information is received. Once CMS has received all of the requested information, CMS sends a letter to the applicant indicating that the second 90-day review period has commenced.

We proposed to codify our current subregulatory requirements for notifying POs of CMS determinations regarding service area and PACE center site expansion applications so the regulations include all of the relevant application timing requirements. Specifically, we proposed to amend § 460.20(a) to make it clear that the notice of CMS determination applies to all three types of applications listed in proposed § 460.10(a), and that the 90-day time limit applies, except for applications to expand the service area or add a new PACE center site.

First, we proposed to delete § 460.20(a)(3) and revise § 460.20(b). Currently, § 460.20(a) states that CMS will approve or deny, or request additional information on, a ''complete application'' within 90 days after submission of the application. We explained in the proposed rule that we believe it is confusing to state that an application is complete if we are requesting additional information. Therefore, we proposed to delete § 460.20(a)(3), which is the provision that describes CMS requesting additional information needed to make a final determination, and we proposed to revise § 460.20(b) to state that an application is only considered complete when CMS receives all information necessary to make a determination regarding approval or denial. We noted that we would not consider the application complete without the required state assurance. We also proposed to revise § 460.20(a) to specify that the time limit for CMS notification of determination is 45 days for expansion applications where a PO seeks to expand its service area or add a new PACE center.

Next, we proposed that § 460.20(b) through (d) be redesignated as § 460.20(c) through (e) and revised as follows. We proposed to revise redesignated § 460.20(c) to describe the process if CMS determines that the application is not complete because it does not include sufficient information for CMS to make a determination. Specifically, CMS would inform the entity that the application is not complete and request the additional information, and within 90 days (or 45 days for a service area or new PACE center expansion application) of CMS receiving all requested information from the entity, CMS would approve the application or deny it and notify the entity in writing of the basis of the denial and the process for requesting reconsideration of the denial. We explained in the proposed rule that we proposed these changes because it is not possible for CMS to make an informed decision to approve or deny an application in situations where we do not have all of the pertinent information. We stated we would consider the SRR, which SAAs conduct to determine the PO's readiness to administer the PACE program and enroll participants, as information necessary to make our final determination and would request that the SRR be submitted in all applicable requests for additional information if we did not already have this information. We further noted that, if more than 6 months elapse between the date of submission of the application and the response to CMS' request for additional information, the entity is required to update the application to provide the most current information and materials related to the application; otherwise, we would consider the application incomplete. We proposed to revise § 460.20(c) accordingly.

Section 460.20(b), which we proposed to redesignate as § 460.20(c), currently outlines the requirements for POs when CMS requests from an entity additional information needed to make an application determination. As noted previously, we proposed to amend the language in this provision to address the different time limits for expansion applications. We also proposed to amend the language to specify that the time limits in § 460.20(a) do not begin until CMS receives all requested information and the application is complete. As we explained in the proposed rule, with the changes to § 460.20(a) and the addition of § 460.20(b), it would no longer be necessary to describe CMS' review process after all requested information has been received; thus, we proposed to remove § 460.20(b)(1) and (2).

Section 460.20(c), which we proposed to redesignate as § 460.20(d), currently implements sections 1894(e)(8) and 1934(e)(8) of the Act and provides that an application for PO status will be deemed approved if CMS fails to act on it within 90 days of the date the application is submitted or the date CMS receives all requested additional information. We proposed to amend this language to specify deemed approval will occur if CMS fails to act after the later of those dates, and that the provisions relating to deemed approval only apply to applications to become a PO, not expansion applications from existing POs. We stated in the proposed rule that this revision is necessary because, as described previously, we proposed to address expansion applications in the regulations, and we wanted to make it clear that only initial applications will be deemed approved if CMS fails to act on them within the required time period. As previously noted, the PACE statutes do not set out requirements for applications submitted by existing POs to expand their service area and/or to add a new PACE center site. We explained in the proposed rule that CMS does not currently employ ''deemed approval'' for expansion applications, and we noted we do not believe there is any reason to do so for these applications at this time. We further proposed to amend this language by specifying that the 90-day period commences after CMS has received a ''complete'' application, as this is consistent with the amendments to § 460.20(a) and § 460.20(b).

Finally, § 460.20(d) currently states that for purposes of the 90-day time limit described in this section, the date that an application is submitted to CMS is the date on which the application is delivered to the address designated by CMS. We proposed to redesignate § 460.20(d) as § 460.20(e), and revise this paragraph to refer to the time limits described in this section to include applications for service area expansions or new PACE center sites.

A discussion of the comments we received on the proposed changes to the CMS notice of determination requirements, and our responses to those comments, appears below.

*Comment:* Commenters questioned the necessity of the proposed provision that would require PACE applicants to update their applications 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. Commenters also questioned whether CMS was proposing to require the applicant to withdraw its application and resubmit an entirely new application, or if CMS would permit less burdensome and timelier ways to update the existing application through submission of additional information. Commenters recommended the latter approach, and suggested allowing 12 months, as opposed to 6 months, to elapse between the date of application submission and the entity's response to the request for additional information before the entity is required to update its application. Commenters also recommended that the submission of additional information not be subject to CMS' quarterly submission timeframes for applications.

*Response:* After careful consideration of the comments, we have reconsidered

the timeframe that would require an update to the application. We agree with commenters that there may be valid reasons for delay in responding to our request for additional information (for example, unexpected delays in construction or licensing of the PACE center, or timing of the SRR); therefore, we accept the recommendation made by commenters and will specify that if more than 12 months, instead of 6 months, elapse between the date of initial submission of the application and the entity's response to our request for additional information, the entity must update the application with the most current information and materials related to the application. This means that, in addition to addressing the additional information requested by us, the applicant must submit all other application-specific documentation that may have changed during the interim 12-month period. We note that, depending on the nature of those changes and updates, there may be circumstances in which the applicant will be required to submit a completely new application; for example, if there is a change in the legal entity that is applying to become a PO.

With respect to commenters' recommendation that the submission of additional information not be subject to quarterly submission timeframes, we note that responses to a request for additional information are not limited to a quarterly submission cycle. While the application itself (initial or expansion) must be submitted on the established quarterly dates, information in response to a request for additional information may be submitted at any time.

*Comment:* We received comments in response to the proposed provision regarding deemed approval of initial applications. One commenter did not believe that an application should be deemed approved due to CMS' inability to review and act on an application within the required timeframes. This commenter believed that all documentation submitted to fulfill an application as complete must be reviewed and approved by CMS without any deemed approval. Other commenters noted that CMS, in the preamble to the proposed rule, stated that it does not believe it is necessary to allow deemed approval for expansion applications, as it has not done so in the past. Commenters requested that CMS reconsider this position and allow deemed approval of applications from POs seeking to expand a service area, with or without adding a new PACE center. While recognizing that CMS has always acted on expansion applications within the timeframes required for initial applications, the commenters stated there is no reason to preclude deemed approval if CMS is unable to act on an expansion application in a timely manner for some reason.

One commenter stated that, in cases in which the deemed approval requirement is triggered, it is still necessary for CMS to issue confirmation that deemed approval took place in order to effectively track the status of the review process.

*Response:* Sections 1894(e)(8) and 1934(e)(8) of the Act require an application for PO status to be deemed approved unless the Secretary, within 90 days after the date of the submission of the application to the Secretary, either denies the request in writing or informs the applicant in writing with respect to any additional information that is needed to make a final determination. The Act further states that, after the date of receipt of any additional requested information from the applicant, the application must be deemed approved unless the Secretary, within 90 days of such date, denies such request. As we noted in the proposed rule, the PACE statutes do not specifically address expansion applications. As such, we proposed to specify in redesignated § 460.20(d) that the deemed approval requirement only applies to entities that submit an initial application. As stated in the proposed rule, we do not currently employ deemed approval for expansion applications and we do not believe there is valid reason to employ deemed approval for expansion applications at this time. We appreciate the recognition from commenters that we have, to date, rendered decisions regarding expansion applications within the timeframes required for initial applications; however, we do not want to be in a position in which a deeming process supersedes our ability to make thoughtful, proactive decisions regarding these expansion applications. Therefore, we are finalizing our proposal that the deemed approval requirement will not apply to expansion applications.

Regarding the comment that we must issue confirmation that an application has been deemed approved, we note that the automated PACE application system sends communications to applicants regarding the status of their application, and applicants would receive formal notification of any deemed approval in the approval letter that accompanies the applicant's executed PACE program agreement. In light of these communications, we do not believe separate CMS confirmation of deemed approval is necessary. However, based on the input received, we will consider modifications to our auto-generated communications to include additional information regarding timeframes for review.

*Comment:* One commenter explained the process one specific SAA must undergo in order to effectuate service area expansions and expansions involving new PACE centers, and suggested that CMS and the SAA consider ways to better coordinate and shorten the timeframes for approval of expansion applications. The commenter noted that CMS has 90 days after submission of the SRR to make a determination with regard to the application and questioned whether it would be possible to allow a PACE center to open immediately upon receipt of the completed SRR.

*Response:* We note that our review timeframe may be 45 or 90 days depending on the type of expansion application. While we seek to review expansion applications as expeditiously as possible, adequate time must be afforded to us to review all aspects of an application, including responses to any requests for additional information, as well as the SRR. As a party to the PACE program agreement, we must carefully review all elements of the application, including the SRR, and therefore, would not consider allowing a PACE center to begin operations immediately upon our receipt of the SRR. We note that, even after we receive the SRR and any information submitted in response to a request for additional information and we determine the application is approvable, we require additional time to amend and execute the PACE program agreement and ensure that proper steps have been taken to accommodate enrollment of participants and payment to the PO. Within the past year, we have significantly expedited the effective date for approvals of expansion applications, often making them effective upon the date of approval of the expansion application.

After carefully considering all comments, we are finalizing § 460.20 as proposed, with one modification. Under § 460.20(c)(2), an entity will be required to update its application if more than 12 months, as opposed to 6 months, elapse between the date of initial application submission and the entity's response to the CMS request for additional information.

5. Service Area Designation (§ 460.22)

As discussed in section III.C.2. of this final rule, we proposed to move the content of § 460.22, in its entirety but with a few revisions, to § 460.12(c).

Therefore, we proposed to delete § 460.22.

A discussion of the comments we received on this proposed change, and our responses to those comments, appears below.

*Comment:* One commenter questioned whether the proposed removal of § 460.22 means that zip code expansions will no longer be required, and if so, whether expansion information will be documented as part of PACE program agreement updates.

*Response:* We assume the commenter is questioning whether expansion applications from POs that seek to expand their approved geographic service area will no longer be required. We address application requirements specific to service area expansions in section III.C.2. of this final rule. However, we wish to clarify that we proposed to move the current content of § 460.22 to § 460.12(c), which is why we proposed to delete § 460.22. We note that a description of the service area will still be required as part of the application, in accordance with existing requirements and documented as part of Appendix C of the PACE program agreement.

*Comment:* A few commenters addressed the provision that states CMS, in consultation with the SAA, may exclude from designation an area that is already covered under another PACE program agreement to avoid unnecessary duplication of services and avoid impairing the financial and service viability of an existing program. One commenter expressed support for this provision. Another commenter expressed appreciation of CMS' goal and emphasized the word ''may'' in this provision, as some degree of competition between PACE programs in the same geographic area may be useful to ensure adherence to minimum quality standards and encourage the provision of quality services.

*Response:* We note that this provision is based on sections 1894(e)(2)(B) and 1934(e)(2)(B) of the Act, and it is not a new provision or revision to an existing provision. Rather, we are simply moving the provision, in its current form, from § 460.22(b) to § 460.12(c)(2). As a result, we proposed to delete § 460.22(b). After considering the comments, we are finalizing this change as proposed.

*Comment:* One commenter expressed support for current provisions that require clearly-defined geographic service areas for both initial and expansion applications. The commenter also expressed the need to ensure flexibility regarding the designation of service areas. The commenter noted that traditional reliance on boundaries defined by county lines or Core Based Statistical Areas (CBSA) may prove arbitrary in terms of reflecting the actual distribution of a population in need of services. The commenter also noted innovations such as telehealth are redefining traditional concepts of a service area, in both rural and urban settings. The commenter stated that flexibility in defining service areas enhances the ability to target PACE services to populations that could support and benefit from coverage by more than one PO; for example, there could be situations in which a new PO seeking to enter a market is willing to introduce innovation or serve a specialized population that an existing PO is unable or unwilling to match.

*Response:* We note that § 460.32(a)(1) allows the service area of a PO to be identified by county, zip code and other means. Therefore, applicants are not necessarily bound by traditional geographic designations. With respect to the comment regarding innovative service delivery approaches that could be considered when defining service areas, we appreciate this input and may consider it as part of subregulatory guidance or rulemaking in the future.

*Comment:* One commenter acknowledged that both the current and proposed regulations require an applicant entity to identify the service area the PACE program wishes to serve, noting, specifically, that CMS, in consultation with SAAs, may exclude an area that is already being served by another PACE program agreement. One commenter noted that Tribal Health Programs (THPs) have a unique relationship with the American Indian/Alaska Native (AI/AN) beneficiaries they are contracted to serve. Specifically, AI/AN beneficiaries have the ability under Medicaid to receive services from a THP, even when the AI/AN is enrolled in a managed care product, and the THP has the right to receive reimbursement for services provided. Therefore, the commenter requested that CMS specify an exception to the service area designation requirement to allow THPs to identify the Indian Health Service (IHS) Service Area in their application, even if a non-Indian PACE program already exists in all or part of that IHS Service Area.

*Response:* We interpret the comment to be specific to a THP that may apply to offer a PACE program. We note that, under § 460.32(a)(1), a service area may be defined by county, zip code and certain other means including tribal jurisdictional area, as applicable, and this is explicitly stated in the PACE application. We further note that the regulatory language currently in § 460.22(b) states that CMS, in consultation with the SAA, may exclude from designation an area that is already covered under another PACE program agreement to avoid any unnecessary duplication of services and avoid impairing the financial and service viability of an existing program. Whether another PO is currently serving a designated service area is therefore a consideration in the potential exclusion of that area, not an absolute requirement for exclusion.

After considering the comments, we are finalizing the changes to § 460.22 as proposed.

6. Submission and Evaluation of Waiver Requests (§ 460.26)

Section 460.26 sets forth the process for submitting and evaluating waiver requests. We proposed to revise current § 460.26(a)(1) and (2) so that § 460.26(a)(1) would state that a PO, or an entity submitting an application to become a PO, must submit its waiver request through the SAA for initial review. Paragraph (a)(1) would also specify that the SAA forwards waiver requests to CMS along with any concerns or conditions regarding the waiver. We proposed that section 460.26(a)(2) would state that entities submitting an application to become a PO may submit a waiver request as a document separate from the application or in conjunction with and at the same time as the application. While we did not propose any policy changes in the proposed rule, we stated that we believed these changes would make the requirements for submission of the waiver request more concise and clear. We noted that we plan to provide additional detail on this part of the process in subregulatory guidance.

Section 460.26(b) states that CMS evaluates a waiver request from a PO on the basis of certain information. We proposed to add ''or PACE applicant'' after ''PACE organization'' because a waiver request can be submitted by an existing PO or a PACE applicant (an entity that has applied to be a PO but is not yet a PO, or a PO applying to expand its service area and/or add a new PACE center site).

A discussion of the comments we received on the proposed changes to the waiver process requirements, and our responses to those comments, appears below.

*Comment:* We received many comments in support of the proposed changes to the waiver submission process language. Commenters also requested clarification on whether waiver requests can be submitted as part of an entity's initial application or

whether the waiver requests have to be submitted to CMS by the SAA.

*Response:* Under our current process, entities submitting an application to become a PO may submit a waiver request either as a separate document or in conjunction with their initial application. We are adding language to § 460.26 to clarify that an applicant may submit a separate waiver request through the SAA or the applicant may submit a waiver request in conjunction with and at the same time as the initial application, now that the application submission process is automated. As previously required, a waiver request submitted with an initial application must include a letter from the SAA indicating the State's concurrence, concerns, or conditions related to the waiver request. We note that our review of any waiver requests submitted in conjunction with the initial application will be reviewed in accordance with the 90-day review period for waiver requests in § 460.28. We are making one additional change to § 460.26(a)(1) to refer to the SAA's concurrence, as well as any concerns or conditions, regarding the waiver, to align that provision with the proposed requirement in § 460.26(a)(2) for waiver requests submitted in conjunction with initial applications.

*Comment:* One commenter expressed concern that we have not included provisions for broader waiver types that address a systematic issue and noted the example of hiring social workers with a bachelor's degree instead of a master's degree in areas where it is difficult to hire a Master's-level social worker. The commenter recommended that POs be afforded the ability to request a blanket waiver, meaning no limitation on the effective period of the waiver, to allow targeted flexibility for a specific, documented purpose, such as in the example cited. In the absence of additional flexibilities, the commenter stated that POs may have to submit multiple waiver requests over time to address the same type of flexibility, which is a time-consuming and costly process for POs.

*Response:* With the exception of the requirements specified in § 460.26(c), POs have broad latitude to request waivers to address localized, systematic issues on a long-term basis, such as the example cited by the commenter, as long as all waiver requirements are met. In addition, we believe the revisions we are making to the regulations in this final rule will result in fewer waiver requests. Specifically, the additional flexibilities we are providing, such as the changes to the IDT requirements at § 460.102, will permit POs to operate their programs with these flexibilities and no longer require POs to request waivers of those requirements. For example, we are finalizing changes to allow community-based physicians to serve as the primary care provider on the IDT. Prior to these regulatory changes, POs would have had to request a waiver of this requirement in order for a community-based physician to function in the role of the primary care physician on the IDT.

*Comment:* One commenter requested that when CMS is seeking to deny a waiver request that the SAA reviewed and supports, there should be provisions in place for consultation with the state before CMS makes a final determination. The commenter acknowledged this practice is already in place; however, the commenter would like it to be codified in the regulations to ensure consistency.

*Response:* We consult with the SAA on all waiver requests and do not believe it is necessary to codify this practice in our regulations. We intend to clarify this practice in future guidance.

After considering the comments, we are finalizing the proposed changes to § 460.26 in part, with modifications to clarify that an applicant may submit a separate waiver request through the SAA, per the quarterly deadlines, or the applicant may submit a waiver request in conjunction with and at the same time as the initial application, and a change to § 460.26(a)(1) to refer to the SAA's concurrence, as well as any concerns or conditions, regarding the waiver.

7. Notice of CMS Determination on Waiver Requests (§ 460.28)

Section 460.28 discusses the timeframes for CMS determination and notification regarding approval or denial of waiver requests. As we explained in the proposed rule, we established this section to implement section 903 of BIPA, which provides in relevant part that the Secretary shall approve or deny a request for a modification or a waiver not later than 90 days after the date the Secretary receives the request. We proposed to retain most of the language in current § 460.28(a), but to specify that the 90-day time limit starts after CMS receives a complete waiver request. We discuss the need for a complete waiver request in subsequent paragraphs. In § 460.28(a), we proposed to revise the heading to ''General,'' delete the reference to a denial being ''in writing,'' and state that CMS will take action on the complete waiver request in the form and manner specified by CMS. We proposed these changes to reflect how we provide notification, whether electronically or in another format. We noted in the proposed rule that CMS would not only provide notification verbally. We proposed to redesignate § 460.28(a)(2) as new § 460.28(a)(3).

We proposed to add a new § 460.28(a)(2) to address conditional approval of a waiver request from a PACE applicant when the application is still pending. We explained in the proposed rule that under CMS' current process, a PACE applicant may request a waiver while its application is still pending and receive either a denial of the waiver request or a conditional approval of the waiver request. The approval of the waiver request is conditioned on the approval of the application. CMS will only issue conditional approvals to entities with pending applications. We noted that issuing a conditional approval enables CMS to adhere to the BIPA 90-day timeframe for making a determination with respect to a waiver request in situations where an application is still under review. Waiver requests that are not associated with a pending application either receive an approval or denial.

In addition, we proposed to remove the language in § 460.28(b) regarding the date of receipt of the waiver, because we believed the proposed changes to § 460.28(a) and (b) make it clear that the 90-day clock will start on the day CMS receives a complete waiver request. We also proposed to change current paragraph (c)(1) regarding deemed approval of a waiver request to refer to CMS failing to act within 90 days of receipt of a complete waiver request, and redesignate it as paragraph (c). We stated that CMS will notify POs to confirm receipt of ''complete'' waiver requests.

We proposed new language in § 460.28(b) regarding additional information requests for waivers. We explained in the proposed rule that unlike sections 1894(e)(8) and 1934(e)(8) of the Act, which give CMS 90 days to request additional information from entities applying to become POs, section 903 of BIPA does not explicitly impose a time limit for CMS to request additional information that is necessary to make a determination on a waiver request. In the 2006 final rule, we stated that there is ''no statutory authority to stop the 90-day clock if additional information is necessary to make a determination on a waiver request.'' (71 FR 71255). We noted in the proposed rule that although we cannot stop the clock, we believe the statute can be read to start the 90-day clock upon CMS' receipt of a complete waiver request. Therefore, we proposed

in new paragraph (b) that a waiver request is complete when CMS receives all information necessary for CMS to make a determination regarding approval or denial. We stated that if CMS determines the waiver request is not complete, CMS would request additional information needed to make a determination. The 90-day clock would start when CMS receives the complete waiver request. We noted that we proposed these changes because it is not possible to make an informed decision to approve or deny a request for a waiver in situations where we do not have all of the pertinent information. We further stated that we believed this change would reduce the administrative burden on CMS, as well as the POs because, currently, CMS denies incomplete waiver requests and POs must resubmit new waiver requests that include the missing information. Under the process we proposed, CMS and the PO would work together to ensure that the request includes all necessary information, which should alleviate the need to resubmit a waiver request.

We explained in the proposed rule that this is similar to the treatment of PACE applications, and we believed consistency in review procedures would be helpful to all parties involved. We also noted that approval of a waiver associated with a PACE application is contingent upon the approval of that PACE application because there is nothing to waive if there is no PACE program. Accordingly, waivers that are submitted for review in conjunction with a PACE application or while a PACE application is being reviewed would only be approved if that application is approved. As previously discussed, we proposed to add a new § 460.28(a)(2) that provides for conditional approval for entities with a pending application to become a PO.

Currently, § 460.28(c)(2) allows CMS to withdraw its approval of a waiver for good cause. We proposed to redesignate this provision as (d)(1) and amend it to provide that CMS ''in consultation with the'' SAA may withdraw approval of a waiver request for good cause. We proposed to add this language because any significant change to the PACE program agreement, which includes waivers, should be made in consultation with the SAA because the SAA also is a signatory of the agreement. We proposed in § 460.28(d)(2) that, if the waiver approval is withdrawn, CMS must notify the PO or PACE applicant and the SAA that approval of a waiver has been withdrawn and specify the reason for withdrawal and the effective date of the withdrawal in the notice. We noted that currently, while the regulation enables CMS to withdraw an approval of a waiver request, it does not require that we notify the PO or PACE applicant and the SAA of the withdrawal, the reason for withdrawal, or the date when the withdrawal would be effective. We stated that we believe this information is critical to the PO or PACE applicant and the SAA because it likely would require a change in operation of the PO or could change how an applicant would operate a PO if its application is approved.

A discussion of the comments we received on the waiver determination and notification process, and our responses to those comments, appears below.

*Comment:* Some commenters requested that we implement a 30-day timeframe to determine if a waiver request is complete and then reduce the 90-day timeframe for review to 60 days. Commenters also expressed that as CMS adds additional flexibilities to the PACE regulations, there may be fewer waiver requests, and some of the commenters requested that CMS reduce the 90-day review period to 60 days.

*Response:* We appreciate the commenters' suggestions. We note that if we consider the waiver request we receive to be complete, the 90-day review timeframe would have started upon receipt of that request. Consequently, it is in our interest, as well as the PO's interest, for us to make this completeness determination promptly, and we do not believe it is necessary to implement a shorter timeframe for making this determination. While we agree with commenters that we anticipate receiving fewer waiver requests in the future due to the additional flexibilities provided in this final rule, we note that the length of time we need to review a waiver request will not be affected by the number of requests received.

*Comment:* One commenter described the process one specific SAA must undergo in order to effectuate service area expansions and expansions involving new PACE centers and suggested that CMS and the SAA consider ways to better coordinate and shorten the timeframes for approval of PO waivers. The commenter noted that CMS has 90 days after submission to complete the review.

*Response:* Section 903 of BIPA provides that the Secretary must approve or deny a waiver request not later than 90 days after receiving the request, and that is the timeframe we established in § 460.28. At this time, we are not in a position to commit to a shorter review period than the established 90-day review period. While we seek to review waivers as expeditiously as possible, adequate time must be afforded to review all aspects of the waiver, including responses to any requests for additional information.

After careful consideration of the comments received, we are finalizing this proposal without modification.

*D. Subpart C—PACE Program Agreement*

1. Content and Terms of PACE Program Agreement (§ 460.32)

Section 460.32 specifies the required and optional content of a PACE program agreement. Under § 460.32(a)(12), a PACE program agreement must contain information about the Medicaid capitation rate and the methodology used to calculate the Medicare capitation rate. This requirement is based on sections 1934(d)(2) and 1894(d)(2) of the Act, which provide that the Medicaid capitation amount and the Medicare capitation amount, respectively, to be applied for a PO for a contract year must be an amount specified in the PACE program agreement for the year.

Section 460.32(a)(12) and § 460.180(b) require the PACE program agreement to specify the methodology used to calculate the Medicare capitation rate, as opposed to the actual rate. The PACE Medicare rate is based on Part A and B payment rates established for purposes of payments to Medicare Advantage organizations and is subject to certain other adjustments (see § 460.180). For the Medicaid capitation rate, however, our current regulations require the PACE program agreement to specify the actual amount negotiated between the POs and the SAA (see § 460.32(a)(12) and § 460.182(b)).

As states are moving toward more managed care delivery systems for the long term care population, some states are redesigning their methodologies for developing PACE Medicaid capitation rates to more closely align with these other managed care delivery systems. Some of the new methodologies result in Medicaid payment variations based on factors such as frailty adjustments and performance incentive payments. Additionally, because many states update their PACE Medicaid capitation rates annually based on the state fiscal year, there are operational challenges associated with updating the PACE program agreement appendices to reflect changes to the Medicaid rates because they are not necessarily updated consistent with a PACE program agreement's contract year. As a result, we stated in the proposed rule that we

believed it is not always practical to include the actual Medicaid capitation rates in the PACE program agreement. Therefore, we proposed to amend § 460.32(a)(12) to require that the program agreement include the Medicaid capitation rates or Medicaid payment rate methodology, as well as the methodology used to calculate the Medicare capitation rate. Medicaid capitation rates are developed and updated by the states (in negotiation with the POs) and approved by CMS. Operationally, states submit documentation to CMS to support their proposed PACE Medicaid capitation rates. CMS reviews the documentation to ensure the rates are in compliance with the requirements of § 460.182, and provides the state with written approval of the rates. The Medicaid capitation rates are then communicated to the POs by the state in writing.

We also solicited comments regarding other modifications we might make to the required content of the PACE program agreement, specifically, those cited at § 460.32(a) and § 460.182(d). We specifically requested 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. Much of the required program agreement content relates to operational components of the PO's program. We explained that our expectation is that POs regularly review and update this information, particularly as it relates to policies and procedures, to ensure its business practices are current, compliant with regulation and guidance, and consistently employed. We solicited comments on whether specific policies and procedures, and other existing requirements, should continue to be part of the PACE program agreement.

A discussion of the comments we received on the PACE program agreement requirements, and our responses to those comments, appears below.

*Comment:* A commenter requested that CMS modify the PACE regulations to allow a PO to enter into a two-way agreement with CMS to provide services to Medicare beneficiaries in states that do not establish PACE as a State option under Medicaid. In these situations, the commenter recommended that CMS require the potential PO to submit the application with a statement by the state regarding which, if any, of the state functions the state is willing to perform; for example, the SRR, nursing home level of care determination, etc.

*Response:* We did not propose any changes to the current PACE program agreement between a PO, CMS and the SAA for the operation of a PACE program. Therefore, we consider this comment to be outside the scope of this rule. However, we note that in the 1999 IFC and the 2006 final rule, we articulated, in great detail, requirements an entity must meet in order to be approved as a PO and the basis for those requirements, including the requirement for a tripartite agreement and rationale for requiring that POs participate in both Medicare and Medicaid (64 FR 66237; 71 FR 71251). As we stated in those rules, the authorizing PACE statutes (sections 1894 and 1934 of the Act) envision active collaboration between federal and state governments in the administration of the PACE program. As described in the 1999 IFC and 2006 final rule, the SAA is responsible for a wide array of functions related to the operations of a PACE program, including: (1) The SRR conducted as part of activities to approve an entity as a PO; (2) assessment of potential participants to ensure nursing facility level of care requirements are satisfied; and (3) cooperation with CMS in the oversight of the PACE program (which includes authority to terminate a PACE program agreement for cause, as a party to the tripartite agreement), among other key activities. As we stated in those rules, it is our belief that a state which has not elected PACE as an optional service would likely be ill-prepared or even unable to perform these critical activities. We concluded in those rules that a Medicare-only program could not meet the fundamental concept of an all-inclusive, integrated, capitated, full-risk program. Our position today has not changed; we continue to believe that the rationale for structuring the PACE program as we have is valid and appropriate.

*Comment:* A number of commenters expressed support for CMS' proposal to modify the current requirement in § 460.32(a)(12) that the Medicaid capitation rate be included in the PACE program agreement. Commenters noted that the proposed change would allow for either the Medicaid capitation rate(s) or the Medicaid payment rate methodology to be included in the PACE program agreement. These commenters stated that the proposed approach effectively streamlines updates to the PACE program agreements and provides states the flexibility to adapt to potential payment rate changes and variations.

*Response:* We thank the commenters for their support.

*Comment:* One commenter recommended that the final rule provide clarity on the level of detail expected in the PACE program agreement for states that opt to include the Medicaid rate methodology. The commenter noted that states already undergo a comprehensive review of their PACE Medicaid rate methodology by CMS annually. Therefore, commenters requested that CMS allow a more general methodology description to be allowed in the PACE program agreement to further the flexibility discussed in the proposed rule and recognize the extensive methodology review process already taking place. The commenter further noted this would avoid the burden of frequent updates to the PACE program agreement while leveraging, rather than duplicating, the comprehensive Medicaid rate review process that CMS already undertakes. The commenter also requested that CMS clarify the timeframe in which a state must update the actual Medicaid capitation rate in the PACE program agreement if the state elects to include the Medicaid rate instead of the methodology.

Another commenter noted that the PACE Medicaid capitation methodology is complex and often confusing and that this change removes any incentive for SAAs to timely ''negotiate'' the monthly capitation amount with POs and produce rate schedules. In addition, the commenter urged CMS to clarify the negotiation requirement to establish the monthly Medicaid capitation amounts. The commenter indicated that in one state, Medicaid rates are set using an actuarial formula, which takes into account regulatory requirements and the state's priorities, which effectively precludes POs from annually negotiating with the SAA. Instead of focusing on regulatory revisions to reflect the status quo, the commenter urged CMS to consider including language to affirmatively require timely Medicaid rate setting for the PACE program and buttress the ability of POs to negotiate rates.

*Response:* We are not specifying the level of detail that the state must include in the PACE program agreement to describe the state's methodology for Medicaid capitation rates. The state must provide enough detail about the Medicaid payment rate methodology to ensure it is in compliance with requirements of § 460.182, but the state will have flexibility in the level of detail that is provided. In December 2015, we released guidance to states regarding the Medicaid rate setting process that outlines submission and timeframe expectations related to development and approval of Medicaid capitation rates under PACE. The PACE Medicaid

Capitation Rate Setting Guide was developed as a resource for states and it includes critical elements of rate setting that incorporate both the state development of the amount that would otherwise been paid if individuals were not enrolled in PACE, and development of the PACE rates. The guide can be found at *https://www.medicaid.gov/medicaid/ltss/downloads/integrating-care/pace-medicaid-capitation-rate-setting-guide.pdf.* We expect to update the guide in the future to provide more detail and clarification in certain areas as necessary.

Additionally, while we do review the state Medicaid rate documentation to ensure that the PACE rates meet all requirements under § 460.182, including that the monthly capitation amount is less than the amount that would otherwise have paid under the state plan if the participants were not enrolled under the PACE program, the state has flexibility in establishing the rate as long as it meets those requirements, which includes the flexibility of negotiating with POs. The process for negotiation of the monthly capitation payment amount between the PO and the SAA varies by state. We do not require a specific process for negotiation as long as the rates meet the requirements of § 460.182(b).

*Comment:* One commenter encouraged CMS to engage with SAAs to determine which components of the PACE program agreement are necessary from the states' perspective. The commenter expressed support for efforts to remove detailed information that changes with some frequency, for example, administrative contacts that are available in CMS' HPMS. It is the commenter's expectation that the PACE program agreement would generally include high-level requirements as opposed to specific program policies and procedures.

*Response:* We appreciate the thoughtful comments and suggestions and will consider the feedback provided as part of possible future rulemaking.

*Comment:* One commenter noted that § 460.34 currently states: ''An agreement is effective for a contract year, but may be extended for additional contract years in the absence of a notice by a party to terminate.'' The commenter recommended this language be modified as follows: ''An agreement is effective for a contract year, but *shall* be extended for additional contract years in the absence of a notice by a party to terminate.''

*Response:* We did not propose any changes to the regulatory provision at § 460.34 regarding the duration of PACE program agreements. Therefore, we consider this recommendation to be beyond the scope of this regulation. However, we may consider this suggestion as part of possible future rulemaking. After considering the comments, we are finalizing the amendment to § 460.32(a)(12) as proposed.

*E. Subpart D—Sanctions, Enforcement Actions, and Termination*

1. Violations for Which CMS May Impose Sanctions (§ 460.40)

To support PACE program integrity and to protect PACE participants, we proposed to amend provisions related to enforcement actions we may take when POs fail to comply with the PACE program agreement and/or program requirements. Currently, § 460.50 identifies some causes for CMS or an SAA to terminate a PACE agreement. Provisions authorize terminating for cause in circumstances including, but not limited to, 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 safety of participants, such as the presence of deficiencies that CMS or the SAA determines cannot be corrected. As we explained in the proposed rule, while current regulations reflect CMS and the SAA's authority to terminate an organization in these circumstances, we believed that we needed to clarify our authority with respect to alternative enforcement actions in the form of sanctions or civil money penalties (CMPs).

We proposed adding a new provision to § 460.40, designated as paragraph (b), to allow CMS the discretion to take alternative actions in the form of sanctions or CMPs when we are authorized to terminate a PO's PACE program agreement. We noted in the proposed rule that, consistent with the authorities in sections 1894(e)(6)(B) and (f)(3) and sections 1934(e)(6)(B) and (f)(3) of the Act, this new provision would align the PACE enforcement structure with the enforcement structure that applies to the Medicare+Choice program, renamed, and hereinafter referred to, as the MA program. The MA program enforcement authorities in sections 1857(g)(3) and (4) of the Act allow CMS the discretion to take enforcement actions in the form of sanctions or CMPs when CMS is authorized to terminate the organization's contract. We proposed that this approach also be utilized in the PACE program, consistent with our statutory authority identified in sections 1894(e)(6)(B) and 1934(e)(6)(B) of the Act, and to promote consistency with the enforcement structure of the MA program. We stated that the change would give CMS the discretion to impose sanctions and CMPs on POs for continued noncompliance, in addition to our current authority to take the most extreme action of termination of the PACE program agreement. To add paragraph (b), we proposed to redesignate the introductory language in § 460.40 to paragraph (a) and redesignate paragraphs (a) through (i) to paragraphs (a)(1) through (a)(9).

2. Civil Money Penalties (§ 460.46)

Due to the redesignation of paragraphs in § 460.40, we also proposed to make technical, non-substantive changes to the citations in this section to reflect the substantive and technical changes discussed above. Specifically, we proposed to amend § 460.46(a)(1) by removing the reference ''§ 460.40(c) or (d)'' and adding in its place the reference ''§ 460.40(a)(3) or (4)''. We proposed to amend § 460.46(a)(2) by removing the reference ''§ 460.40(e)'' and adding in its place the reference ''§ 460.40(a)(5)''. We also proposed to amend § 460.46(a)(3) by removing the reference ''§ 460.40(f)(1)'' and adding in its place the reference ''§ 460.40(a)(6)(i)''. These changes reflect the new numbering of § 460.40 that was discussed previously.

Additionally, we proposed to revise § 460.46(a), in accordance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act) (Sec. 701 of Pub. L. 114–74). The 2015 Act requires agencies to adjust the civil money penalties annually for inflation. The Department of Health and Human Services will publish all of the Department's adjusted CMP amounts at 45 CFR part 102. To ensure transparency, we proposed revising § 460.46(a) to state that the penalty amounts are adjusted for inflation and citing to 42 CFR 1003.102.

The following is a summary of the public comments we received on the proposed provisions regarding sanctions, enforcement actions, and termination, and our responses to comments.

*Comment:* Commenters were supportive of our proposed revisions. A few commenters mentioned that allowing sanctions or CMPs to be taken prior to termination would help POs have time to correct identified issues of noncompliance. Other commenters, while supportive, cautioned CMS to consider the size and financial stability of POs prior to implementing a sanction or CMP, stating that a large CMP or enforcement action could effectively

drive a PO out of business. One commenter recommended that CMS perform a risk benefit analysis prior to implementing a sanction or CMP to ensure the benefit outweighed the potential risk.

*Response:* We agree with these commenters that revising the regulations to enable us to take enforcement actions other than termination will be beneficial to POs by allowing them time to correct deficiencies. We appreciate commenters concerns regarding the potential adverse impact of CMPs and sanctions on POs. We intend to use the new range of penalties in a manner that appropriately accounts for the size and structure of the PO subject to the enforcement action.

*Comment:* A few commenters referenced SAAs. One commenter requested clarification on how the SAA and CMS would work cooperatively on enforcement actions, and if the SAA would be informed prior to a sanction being placed on a PO. Another commenter requested that CMS modify the regulatory language in § 460.40(b) to say that either CMS or the SAA may take a sanction or CMP. The same commenter requested that any money collected from a CMP be split evenly between CMS and the state. Lastly, one commenter requested that we add a new paragraph (c) to the regulation that discusses a state's authority to take enforcement actions based on State laws and regulations.

*Response:* We are committed to maintaining a close partnership with SAAs in overseeing POs. When taking enforcement actions, we will notify the SAA prior to taking the action, as appropriate. However, we are not modifying the regulatory language in the new § 460.40(b) to address SAAs' ability to take sanctions or CMPs. This regulatory language is aligned with sections 1894(e)(6)(B) and 1934(e)(6)(B) of the Act, which do not address the state's ability to take an enforcement action or require consultation with the SAA before imposing sanctions or CMPs, and we believe that we should keep the language similar in this regulation. We are also not accepting the suggestion to add a new paragraph into the regulation to address a state's ability to use state laws and regulations to take its own enforcement actions. We do not believe this level of detail is needed, as nothing in this regulation would prevent a state from using its own legal authority to impose a state enforcement action on a PO. However, we encourage states to coordinate with us prior to taking any enforcement actions against POs based on state authority. Also, while we appreciate the commenter's request that we split CMP money between the states and CMS, we are not authorized to dictate where that money goes, and cannot make that change.

*Comment:* A few commenters, while supportive of the proposed modification to our enforcement provisions, stressed the importance of consistency in audits, especially if audit findings are used in enforcement actions against POs. One commenter questioned what the reference to ''continued non-compliance'' meant, and whether that could mean repeat audit findings.

*Response:* In the proposed rule, we discussed the regulations regarding termination of a PACE program agreement, and that one of the reasons for termination was ''continued non-compliance'' which is discussed in 42 CFR 460.50(b). In the proposed rule, we noted that our proposed expansion to our enforcement authority would allow us to take other enforcement actions, outside of termination, for continued non-compliance. We define continued non-compliance as any instance in which a PO has been made aware it is not in compliance with a regulation or requirement, and the PO has failed to correct that issue within a reasonable period of time, or has repeated uncorrected deficiencies. What will constitute a reasonable period of time for correction may depend on the severity of non-compliance noted by CMS or the SAA. We want to clarify that while continued non-compliance may be identified through repeat audit findings, audits would not be the only source of information to inform an enforcement action. Although continued non-compliance could be revealed through audits, it could also be discovered through routine account management monitoring, quality reporting, or any other avenue in which CMS or the SAA discovers these issues. However, audits are one of the ways we would measure continued non-compliance and we agree that audit consistency is very important. We continue to make process improvements to PACE audits, including utilizing a revised audit protocol, continuing to refine and update internal auditor tools, utilizing a national audit consistency team, and implementing intensive auditor training specific to PACE.

After considering public comments, we are finalizing the changes to §§ 460.40 and 460.46 as originally proposed with the following technical changes. First, in § 460.46, we are making a technical change to the citation in the proposed note from 45 CFR 1003.102 to 45 CFR part 102, and including the language regarding inflation in the regulatory text and not as a note as originally proposed. Second, in § 460.40, we are redesignating paragraph (j) that was established in the November 15, 2016 **Federal Register** (81 FR 80561) as part of the final rule entitled, ''Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements'' and later modified in the April 16, 2018 final rule entitled ''Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee for Service, the Medicare Prescription Drug Benefit Programs and the PACE Program'' (83 FR 16756), as paragraph (a)(10). Finally, we note that the proposed regulation text for § 460.40(a)(3) included language concerning the criteria for sanctions even though our intention was solely to redesignate the paragraph. Therefore, we are modifying the final rule to remove the language regarding discrimination on the basis of an individual's functional, cognitive or psychosocial status, which was inadvertently included, redesignate the paragraph, and restore the language that refers to discrimination in enrollment or disenrollment among Medicare beneficiaries or Medicaid beneficiaries, or both, who are eligible to enroll in a PACE program, on the basis of an individual's health status or need for health care services.

*F. Subpart E—PACE Administrative Requirements*

1. PACE Organizational Structure (§ 460.60)

Sections 1894(a)(3)(A)(i) and 1934(a)(3)(A)(i) of the Act require a PO to be (or be a distinct part of) a public entity or a private, nonprofit entity organized for charitable purposes under section 501(c)(3) of the Internal Revenue Code of 1986. We implemented these provisions in § 460.60(a), which provides that a PO must be, or be a distinct part of, either (1) an entity of city, county, state, or Tribal government or (2) a private, not-for-profit entity organized for charitable purposes under section 501(c)(3) of the Internal Revenue Code of 1986, and it may be a corporation, a subsidiary of a larger corporation, or a department of a corporation. In this discussion, we will

refer to all entities that meet this standard as not-for-profit entities.

Sections 1894(h) and 1934(h) of the Act direct the Secretary to waive the requirement that a PO be a not-for-profit entity in order to demonstrate the operation of a PO by private, for-profit entities. Section 4804(b) of the BBA of 1997 requires the Secretary to provide a report to Congress on the impact of the demonstration on quality and cost of services, including certain findings regarding the frailty level, access to care, and the quality of care of PACE participants enrolled with for-profit POs, as compared to not-for-profit POs. Section 4804(b)(2) of the BBA of 1997 requires the report to Congress to include findings on whether any of the following four statements is true with respect to the for-profit PACE demonstration:

- The number of covered lives enrolled with entities operating under demonstration project waivers under sections 1894(h) and 1934(h) of the Act is fewer than 800 (or such lesser number as the Secretary may find statistically sufficient to make determinations respecting findings described in the succeeding subparagraphs).
- The population enrolled with such entities is less frail than the population enrolled with other POs.
- Access to or quality of care for individuals enrolled with such entities is lower than such access or quality for individuals enrolled with other POs.
- The application of such section has resulted in an increase in expenditures under the Medicare or Medicaid programs above the expenditures that would have been made if such section did not apply. (We refer to these statements collectively as the BBA statements.)

Under sections 1894(a)(3)(B)(ii) and 1934(a)(3)(B)(ii) of the Act, after the date the report is submitted to Congress, the requirement that a PO be a not-for-profit entity will not apply unless the Secretary determines that any of the BBA statements are true.

In 2008, Mathematica Policy Research completed a study of the permanent not-for-profit POs.[5] An interim report to Congress based on this study was submitted in January 2009. At the time of the 2008 Mathematica study, no for-profit entities had enrolled in the PACE demonstration. Therefore, neither report assessed a for-profit PACE population nor did the interim report address the BBA statements.

From 2012 to 2013, Mathematica, under contract with CMS, conducted a study to address quality of and access to care for participants of for-profit POs, specifically focusing on the third BBA statement. The 2013 Mathematica report also included information that provided insight into the first and second BBA statements.[6] Based on the two Mathematica studies, HHS prepared and submitted the report to the Congress on May 19, 2015. A copy of the report to Congress is available at *https://innovation.cms.gov/Files/reports/RTC_For-Profit_PACE_Report_to_Congress_051915_Clean.pdf.*

As detailed in the report, HHS could not conclude that any of the four BBA statements were true. First, the number of covered lives enrolled with for-profit POs was not fewer than 800, and the sample size for the survey examining BBA statements two and three was large enough to make statistically significant determinations of differences. The report stated that HHS could not conclude that for-profit PACE participants are less frail than not-for-profit PACE participants. It also stated that HHS could not conclude that for-profit PACE participants experienced systematic adverse differences in quality of care or access to care as compared to not-for-profit PACE participants. Finally, expenditures were equal between for-profit and not-for-profit POs after controlling for beneficiary risk score, organization frailty score, and county rates, so there would not have been an increase in expenditures if participants in the for-profit POs had been enrolled with a not-for-profit PO.

Based on the findings in the report to Congress, we determined that under sections 1894(a)(3)(B) and 1934(a)(3)(B) of the Act, the requirement that a PO be a not-for profit entity would no longer apply after May 19, 2015 (the submission date of the report to Congress). Because the statutory not-for-profit restriction no longer applies, in the proposed rule, we proposed to remove the corresponding restriction in § 460.60(a) in its entirety. We also proposed to redesignate § 460.60(b), (c), and (d) as § 460.60(a), (b), and (c), respectively.

A discussion of the comments we received on the proposal to remove the not-for-profit restriction in § 460.60(a), and our responses to those comments, appears below.

*Comment:* Commenters expressed concerns about CMS allowing for-profit entities to be POs. Many commenters believed that although the evaluation of the for-profit PACE demonstration found no significant reasons to restrict PACE to not-for-profit entities, CMS should continue its evaluation to identify and better understand any potential differences driven by ownership by a for-profit entity and to ensure that regulatory oversight is applied uniformly to all POs as it pertains to service utilization, participant frailty and outcomes and costs and experience. Other commenters recommended CMS consider requiring all for-profit POs to meet a ratio of services to revenues, similar to the medical loss ratio requirements set forth in the final rule published in the May 6, 2016 **Federal Register** (81 FR 27498) entitled, ''Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability.'' One commenter recommended CMS consider continuing its evaluation for up to 3 years for the for-profit POs. Another commenter supported the change to allow for-profit entities to be POs.

*Response:* As a result of the findings in the May 19, 2015 report to Congress, sections 1894(a)(3)(B) and 1934(a)(3)(B) of the Act state that the requirement that a PO be a not-for-profit entity will no longer apply. The findings of the report did not suggest that we establish different requirements for POs based on their profit status, and we see no basis for applying a different set of requirements, such as medical loss ratio requirements, to for-profit POs. Consequently, the PACE regulations and requirements apply equally to all POs whether they are not-for-profit or for-profit. We have no reason to believe that the results of the evaluation would change if we added additional years to the study. We note that the majority of active POs are not-for-profit entities and most new applicants represent not-for-profit entities.

As a result of the comments, we are making no changes to our proposal and finalizing this provision as proposed.

In addition, we proposed to revise current paragraph (d)(3) (redesignated paragraph (c)(3)) regarding changes in the organizational structure of a PO and add a new paragraph (d) to address PO change of ownership (CHOW). Section 460.60(d)(3) currently provides that a PO planning a change in organizational structure must notify CMS and the SAA, in writing, at least 14 days before the change takes effect. We have stated in

[5] A copy of the 2008 Mathematica study results can be found here: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Downloads/Beauchamp_2008.pdf.*

[6] A copy of the 2013 Mathematica study results can be found here: *https://innovation.cms.gov/Files/reports/pace-access-qualityreport.pdf.*

guidance that a change in organizational structure is one that may affect the philosophy, mission, and operations of the PO and affect care delivery to participants, and would include any CHOW (see PACE Manual, Ch. 2, § 20.3).

In the 1999 IFC (64 FR 66241), we required POs to notify both CMS and the SAA at least 60 days prior to any change in their organizational structure and obtain advance approval for any change that involved a CHOW. In the 2006 final rule (71 FR 71264), we discussed the comments we received on this provision and explained it was not our intent to require POs to notify CMS and the SAA in writing every time there was a change in personnel or a change in the line of reporting of direct participant care staff. Based on comments that the 60-day timeframe was unnecessary, we elected to change the requirement to the 14-day requirement that is currently in place. We also deleted the requirement that changes in organizational structure must be approved in advance by CMS and the SAA, agreeing with commenters that POs have the ability to make such business decisions based on their individual circumstances. As CMS and the SAA are responsible for the health care provided to participants, we retained the 14-day notification requirement in § 460.60(d)(3) to allow CMS and the SAA sufficient time to monitor whether the change is having a substantial impact on the participants or their care. However, we reiterated that in the event of a CHOW, we would apply the general provisions described in the Medicare Advantage regulations at § 422.550.

Based on our experiences with PO CHOW since we published the 2006 final rule, we stated in the proposed rule that we no longer believed 14 days gives us enough time to review and process a CHOW. A CHOW is significantly different from other organizational changes in that it results in the acquiring entity assuming the responsibilities under the PACE program agreement. We explained we need additional time to determine whether the acquiring entity meets statutory and regulatory requirements for entering into a PACE program agreement. We noted that our ultimate responsibility is to the PACE participants, and we need to ensure that an entity is able to assume and fulfill the responsibilities of a PO under the PACE program agreement.

Moreover, we noted that the process to effectuate a CHOW transaction in our systems requires more time than the 14-day timeframe in the current regulation. For example, a minimum of 6 weeks is needed to effectuate changes in our payment systems for the new owner. A 60-day advance notification requirement is more consistent with that timing. We also stated that we wanted our regulations to be clear that the requirements in 42 CFR part 422, subpart L (Effect of Change of Ownership or Leasing of Facilities During Term of Contract), which apply to MAOs under the Medicare Advantage program, apply to POs in a CHOW scenario. Therefore, we proposed to amend newly redesignated paragraph (c)(3) to indicate that the 14-day timeframe does not apply to a CHOW, and to add new paragraph (d), which would specify that a PO planning a 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. We stated that we believed this proposed change would provide the time we need to determine if the entity acquiring the PO meets all PACE requirements and would be able to continue providing quality care to the participants of the PO, and to reflect the change in our systems. We also noted that we believed the amended language as proposed would provide greater clarity to POs as to the requirements that will apply in CHOW scenarios. We stated that we believed the Medicare Advantage requirements for a CHOW in 42 CFR part 422 subpart L, are appropriate for the PACE program, and we will only enter into a PACE program agreement with an entity that is determined to meet PACE program requirements.

For purposes of the proposed provision, any CHOW as defined in § 422.550(a), such as an asset transfer, a merger, or change in partnership, would require a novation agreement, where the contract is substituted for the former contract. We explained that POs will need to follow all CHOW requirements in 42 CFR part 422, subpart L, and must submit all of the necessary documents to CMS for review within the allotted timeframes. Upon CMS' determination that the conditions for CMS approval of a novation agreement are met, a new PACE program agreement will be executed with the acquiring entity.

A discussion of the comments we received on the CHOW proposal, and our responses to those comments, appears below.

*Comment:* A few commenters stated the definition of a CHOW may encompass situations where the PO's parent entity or supporting entity undergoes a restructuring which has no impact on the PO itself. They also questioned if the 60-day notice and related requirements would apply in a restructuring of the PO's parent entity. The commenter suggested that, in these types of situations, the PO should not have to submit advance notice and comply with the requirements of 42 CFR part 422, subpart L.

*Response:* POs may contact us if they have questions on the applicable requirements and whether a particular scenario is a CHOW or a different type of change in organizational structure. If a PO is planning a CHOW as described in § 460.60(d) then the PO must follow the regulations at § 460.60(d) and provide the required notification.

*Comment:* A commenter requested that CMS clarify if the novation agreement is similar to the PACE program agreement.

*Response:* The novation agreement and PACE program agreement are two separate and distinct documents. The novation agreement is an agreement between the current owner of the PO, the prospective new owner, and us under which we recognize the new owner as the successor in interest to the current owner's PACE program agreement. The PACE program agreement will be the successor's PACE program agreement with CMS and the SAA for the operation of a PACE program by the successor PO.

*Comment:* Many commenters supported the proposal to expand the notification timeframe for a CHOW from 14 days to 60 days. One commenter requested that we consider the SAA's needs for advance notification for CHOW scenarios and add additional time to our requirement for notification.

*Response:* We work closely with the SAA as the third party to the PACE program agreement. We expect that as POs are seeking to undergo CHOW transactions that they communicate with the SAA prior to or at the same time as they communicate with us. We will consider the recommendation to allow for additional time to notify the SAA as part of future rulemaking or guidance.

*Comment:* A commenter requested that we limit the requirement for an entity to complete a PACE application for purposes of a CHOW as discussed in the HPMS PACE CHOW memo, Guidance on Notification Requirements for PACE Organization Change of Ownership, dated February 18, 2016, to apply only to those entities that have no experience with PACE program operations. Another commenter suggested that the successor in interest to the PACE CHOW should not have to go through the PACE application

process, but did not suggest an alternative for the qualification process.

*Response:* We want to reiterate our policy that in order for an acquiring entity to become qualified as a PO, the entity must follow both the CMS and the specific state's PACE application submission process. The application process provides a level of assurance to us, as well as the SAA, that the successor in interest to the PO has the ability to assume the obligation to provide care to the vulnerable population in PACE.

*Comment:* One commenter expressed concern that if a PO is seeking a CHOW due to a financial hardship or experiencing other difficulties, requiring the acquiring entity to become qualified through the PACE application process may make it impossible to prevent actions such as a PACE termination.

*Response:* We appreciate the comment and will continue to work with POs that are in these types of hardship situations to help ensure that their participants continue to receive proper care. Even though we have designated timeframes to complete the application approval process, when we are made aware of these types of extenuating circumstances, we work closely with the PO and the SAA to process the application as quickly as possible and prevent negative impact to the participants.

We appreciate the commenters' recommendations and will consider them as we develop subregulatory guidance on PO CHOWs. We will continue to require all entities that are not currently approved POs, but would like to be the successor in interest to a PO, to become qualified as a PO through our PACE application process. The PACE application process is an administrative process with established requirements that all entities have to meet in order to qualify as a PO. This application process demonstrates to us and the SAA that the successor in interest to the PO is qualified to be a PO and will maintain arrangements to comply with the legal and regulatory requirements for PACE and other requirements imposed under the PACE program agreement. This allows us to maintain a consistent qualification process for all entities. We are finalizing the CHOW requirements as proposed.

2. Governing Body (§ 460.62)

Section 460.62 focuses on the ability of the PO's governing body to provide effective administration in an outcome-oriented environment. As we have previously explained in the 1999 IFC (64 FR 66241) and the 2006 final rule (71 FR 71264), the governing body guides operations and promotes and protects participant health and safety, and it is legally and fiscally responsible for the administration of the PO. Additionally, the governing body must create and foster an environment that provides quality care that is consistent with participant needs and the program mission. To that end, we proposed to revise the language in § 460.62(a)(7) and to add new paragraph (a)(8). Currently, § 460.62(a)(7) references a ''quality assessment and performance improvement'' program. In addition to replacing that term with ''quality improvement,'' as discussed in section II.A. of this final rule, we also proposed to add a reference to the quality improvement program requirements in § 460.130, to make it clear that the governing body is ultimately responsible for ensuring the PO meets those requirements.

As we did not receive any comments on these proposed changes, we are finalizing this provision as proposed.

In addition, as discussed later in this section, we proposed in a new § 460.63 to require that all POs adopt and implement effective compliance oversight. Because the governing body is both legally and fiscally responsible for administration of the PO, and is responsible for ensuring that the organization provides quality care (see § 460.62(a)), we stated that we believed adoption and implementation of compliance oversight requirements is the responsibility of the governing body. We noted that having legal responsibility over the governance of the organization requires ensuring that the organization complies with federal and state regulations, adheres to contract requirements, and minimizes waste and abuse. To that end, we proposed to add a new § 460.62(a)(8) that specifies the governing body of the PO must have full legal authority and responsibility for adopting and implementing effective compliance oversight as described in § 460.63.

As discussed in detail in the following section, we received several comments on our compliance oversight proposal and as a result of those comments, we have decided not to finalize certain aspects of that proposal at this time, in order to allow CMS additional time to evaluate the potential burden that implementing certain aspects of the compliance oversight provision might have on POs. Relatedly, based on these comments and to allow additional time to evaluate the potential burden, we are not finalizing the proposal to add a new § 460.62(a)(8) specifying that the governing body of the PO must have full legal authority and responsibility for adopting and implementing the compliance oversight program.

3. Compliance Oversight Requirements (§ 460.63)

In the proposed rule, we discussed the compliance programs required under the Medicare Advantage (MA) and Medicare Part D programs, and noted that those programs have long been recognized as key to protecting against fraud, waste, and abuse. The importance of these programs has been highlighted by several of our oversight bodies. As is authorized by sections 1934(f)(3) and 1894(f)(3) of the Act, we proposed to adopt compliance oversight requirements in the PACE regulations. Specifically, at new § 460.63, entitled ''Compliance Oversight Requirements,'' we proposed to require each PO to have a compliance oversight program that is responsible for monitoring and auditing their organization for compliance with our regulations. Additionally, we proposed to require POs to have measures that prevent, detect and correct non-compliance with CMS' program requirements, as well as measures that prevent, detect, and correct fraud, waste, and abuse.

In determining what compliance oversight CMS should require of all POs, we considered as potential models the compliance program requirements for Medicare Part C organizations at § 422.503(b)(4)(vi) and the compliance program requirements for Part D sponsors at § 423.504(b)(4)(vi). POs offering qualified prescription drug coverage under Part D are already required to have a compliance program as a part of their Part D benefit, however, specific requirements of the Part D compliance program were waived for all POs. The Part D application took into account PACE as a direct care provider, as well as a payer, and it weighed the importance of maintaining compliance with CMS regulations with the need for flexibility as a direct care provider. All Part D compliance program elements were waived except the two elements that we proposed.

In § 460.63, we proposed to establish that the two elements of a Part D compliance program required of POs participating in Part D will become compliance oversight requirements for the PO as a whole. Specifically, we proposed to require each PO to adopt and implement effective compliance oversight, which includes measures that prevent, detect and correct non-compliance with CMS' program requirements, as well as measures that prevent, detect and correct fraud, waste and abuse that would 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-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensuring ongoing compliance with our requirements. As part of the system for promptly responding to compliance issues, we also proposed the requirements that a PO: (1) Conduct a timely, reasonable inquiry if it discovers evidence of misconduct related to payment or delivery of items or services, (2) conduct appropriate corrective actions in response to the potential violation (for example, repayment of overpayments or disciplinary actions against responsible employees), and (3) have procedures to voluntarily self-report potential fraud or misconduct to CMS and the SAA. We noted that the PO should already have these elements implemented for their Part D benefit to comply with the Part D regulations, but they would need to expand these efforts to cover all of the services provided by the PO.

As we explained in the proposed rule, POs are not currently required to conduct internal organization wide monitoring or auditing efforts. Through our experiences with MA and Part D organizations, we stated that we believed conducting monitoring and auditing is key to identifying and correcting issues of non-compliance with CMS requirements. We noted that we believed that by adding these two compliance oversight provisions we are balancing the duty of a PO to ensure compliance with CMS requirements with the need for flexibility as a provider of service. We stated that POs will also benefit from improving their ability to identify and correct compliance risks within their own organization.

Additionally, we proposed to require the PO to implement appropriate corrective action in response to any identified issues of non-compliance that POs may discover. We noted that, if finalized, we intended to verify compliance with this new requirement through monitoring or auditing of the PO.

We received public comments from POs, states and advocacy groups which were supportive of the effort to ensure appropriate protections are in place, but cautioned CMS about the potential burden associated with implementing these provisions. We analyzed our proposal and believe that the majority of the burden on POs associated with the proposed compliance oversight requirements is due to the first proposed element, the requirement that a PO develop and implement a system for monitoring and auditing their PACE operations. While we consider it a best practice for a PO to adopt a compliance program that includes conducting internal monitoring and auditing, we are not finalizing our proposal to require the PO to adopt a system for routine monitoring and auditing of the PO and its contractors at this time in order to further evaluate the potential burden of this proposal on smaller organizations. As Part D plan sponsors, POs must still conduct monitoring and auditing of their Part D benefit as required under 42 CFR 423.504(b)(4)(vi)(F). The second proposed element of the compliance oversight requirements, which requires promptly responding to non-compliance and voluntary reporting of identified issues, does not pose a significant burden on a PO. Therefore, we are finalizing the second element of this provision which would require POs to correct identified non-compliance and voluntarily report fraud and/or potential misconduct to CMS and the SAA. In large part, POs may utilize their already established Part D system to comply with these new requirements for responding to, correcting and reporting non-compliance and potential fraud, and because we are not increasing the scope of a PO's monitoring responsibilities, we anticipate only a minimal burden on the organization by implementing this modified provision.

The following is a summary of the public comments we received on the proposed compliance oversight requirements in new § 460.63 and our responses to comments. As a result of these comments, we are finalizing this provision in part.

*Comment:* A majority of commenters were supportive of our proposal to require POs to adopt a compliance oversight program. Commenters noted that adding compliance oversight requirements is an important step to ensuring POs are able to stop non-compliance and take appropriate corrective action. These commenters noted that this proposal would help ensure the safety of participants, and protect against fraud, waste and abuse.

*Response:* We appreciate commenters' support and agree that implementing a compliance oversight program is a best practice for all organizations, big or small, in order to ensure compliance with federal and state regulations. We hope that POs will consider increasing the scope of their monitoring and auditing efforts as part of their effort to ensure they are compliant with our requirements. We are not, however, finalizing the first element of our proposal which would have required POs to expand the scope of their monitoring efforts. Instead, we are only finalizing the second element, which requires POs to respond, investigate and correct non-compliance as it is identified. While we further evaluate the implications of a required compliance oversight program on the unique PACE model of care, we will continue to assess potential risk to participant safety through auditing and account management oversight, and address any identified fraud, waste and abuse issues as needed.

*Comment:* Multiple commenters raised concerns over the potential burden that implementing this provision would cause POs. Commenters stated that there are significant differences between MA/Part D organizations and POs; including the fact that MA/Part D organizations tend to have larger staffs and greater resources, as well as different program structures, which would make implementing this proposal more challenging for POs. Other commenters suggested that the burden on smaller organizations and rural organizations would be especially significant. Most commenters also requested that, if CMS finalizes this provision, that the implementation date be no earlier than 12 months following the regulation becoming final in order to allow organizations the appropriate time to determine how to appropriately implement a compliance oversight program and allocate resources. Several commenters suggested that CMS had underestimated the cost of implementing a compliance oversight program in PACE. One commenter requested that CMS work closely with stakeholders to determine technical assistance needs and practical implementation schedules before enacting this proposal.

*Response:* We appreciate commenters' concerns regarding the potential burden this provision may cause for POs. We have a significant policy interest in further assessing how to integrate an effective compliance oversight program,

as well as the potential burden and benefits related to expanding this provision across the PACE program. In order to minimize the potential burden associated with this provision, we re-analyzed the burden estimates and believe that the majority of costs are associated with the first element of our proposal, the element that would require POs to expand their auditing and monitoring efforts to cover their entire operation. While we consider it a best practice to conduct internal auditing and monitoring to identify non-compliance with PACE requirements, we are not finalizing that element of this provision at this time while we further evaluate the implications of this proposal on the unique PACE model of care. We are, however, finalizing the second element which would largely allow organizations to use their already established system to respond to and correct any non-compliance discovered in the POs. We anticipate only a minimal burden in finalizing this element and believe such efforts can be implemented in the 60 days following publication of the final rule.

*Comment:* Several commenters posed questions regarding the structure or administration of a compliance oversight program in PACE. Two commenters questioned if POs would be required to submit their compliance oversight program to CMS for approval. The same two commenters questioned if CMS would require the POs to implement specific structures, policies or procedures for the compliance oversight program. Another commenter questioned if CMS would offer technical assistance to POs.

*Response:* We appreciate the opportunity to provide clarification on this proposal. We understand that POs are both payers, as well as direct care providers. We also understand that POs vary greatly in size, structure and resources. As such, we believe that a PO should continue to be free to develop a compliance oversight program that works best for their specific organization. POs are already required to have systems in place to correct identified non-compliance and voluntarily report fraud or potential misconduct to us for their Part D benefit, and we do not anticipate that substantial changes would need to be made to the structure of such systems based on this provision as finalized. Additionally, while we would be willing to provide technical guidance to POs, we do not expect to collect documentation regarding the structure of a PO's compliance oversight program or provide an approval process. Instead, POs will have flexibility in designing their own compliance oversight programs so long as they ensure they are satisfying the requirements in the new § 460.63.

*Comment:* A few commenters questioned how CMS would monitor these compliance oversight programs in PACE. One commenter suggested CMS conduct rigorous monitoring of the compliance oversight programs. Another commenter questioned if CMS would validate the monitoring that POs did under their compliance oversight programs. One commenter requested that CMS ensure that any monitoring of the compliance oversight program is done consistently across regions.

*Response:* We may begin monitoring compliance with the requirements in § 460.63 as finalized during audits or other communications with POs. We agree that CMS monitoring should be done consistently and we intend to develop specific guidance for auditors or other personnel in CMS.

*Comment:* Several commenters expressed their support for our proposal to reduce the frequency of CMS audits and characterized it as being in exchange for requiring POs to develop their own compliance oversight requirements.

*Response:* We thank the commenters for their support. While we proposed both to decrease the frequency of our audits and to increase POs' self-monitoring, these policies were each intended to stand on its own and were not intended to be an exchange. While we are not finalizing the element of the proposed compliance oversight requirements that would have required POs to monitor and audit all operations, we believe that this is a best practice and would encourage organizations to expand the scope of their current monitoring and auditing efforts. We are finalizing the second element within this provision in order to ensure POs are promptly responding to, investigating and correcting potential compliance problems as they are identified. Separately, we are also finalizing our proposal to reduce the frequency of reviews by us in cooperation with the SAA under § 460.192, as discussed in the final rule below in Subpart K—Federal/State Monitoring.

*Comment:* One commenter recommended that the compliance oversight requirements for POs include all seven elements of the MA and Part D compliance programs, rather than just the two we proposed.

*Response:* We thank this commenter for the suggestion. While we believe that compliance programs are beneficial to all organizations, regardless of size, we decided at this time not to require POs to implement the seven compliance program elements required under MA and Part D. Under the Part D regulations, POs are required to have two of the seven elements of a compliance program implemented for their Part D benefit, but the other five elements are waived for POs. While we will continue to engage POs in discussions regarding the benefits of robust compliance programs, at this time we do not believe it is appropriate to require POs to implement the seven elements of the MA/Part D compliance program.

*Comment:* Several commenters suggested modifications to our compliance oversight proposal. A few commenters expressed concern with the potential burden of a compliance oversight program in PACE, and recommended we consider modifying the PACE compliance oversight program to account for the small size of some POs. These commenters recommended we refer to the OIG guidance on compliance programs for individual and small physician practices (see 65 FR 59434 through 59452).

*Response:* We appreciate these concerns and consistent with the OIG guidance cited by commenters, we took the size and structure of POs into account when proposing compliance requirements for PACE. As we mentioned in the proposed rule (81 FR 54677), we balanced the need for POs to maintain compliance with program requirements with the fact that they need flexibility as direct care providers. We initially proposed that of the seven compliance program elements in the MA and Part D programs, only two of these elements should be regulatory requirements for all POs. However, after reviewing the comments received, and because we have a significant policy interest in preventing undue burden, we are only finalizing one of the two proposed required elements. We believe there is a need for organizations to be able to identify non-compliance and fraud, waste and abuse, and to take corrective action when an issue is discovered. We also believe that since all POs already have a system in place to respond to identified compliance issues related to the Part D benefit, that finalizing this element will only create a minimal burden on POs.

*Comment:* Two commenters requested clarification on whether the PO must operate the compliance oversight program, or whether a parent organization of the PO could comply with the compliance oversight requirements on behalf of the PO.

*Response:* The regulation as finalized imposes compliance oversight

requirements on the PO, but we intended for these requirements to provide flexibilities for POs. Each PO must have procedures and an effective system for promptly responding to compliance issues and correcting problems, but we will not dictate what that system should look like or how it should be structured. Since POs are already required to have a system for responding to compliance concerns in their roles as Part D sponsors, we expect that many organizations will adapt their existing system to meet the PACE program requirements. However, the individual organization has discretion to choose to develop its compliance oversight program, including whether or not the compliance oversight program is run through the PO or another entity (such as a parent organization).

As discussed previously, a majority of commenters were supportive of our proposal to implement a compliance oversight program in PACE, while some commenters raised concerns regarding implementation and the associated burden of a compliance oversight program on small, direct care organizations. We agree with these commenters that further evaluation should be done to determine the potential burden associated with implementing this provision as proposed, but we believe that finalizing the second element within this provision would not impose a significant burden on organizations as, in large part, they may be able to use the systems for respond, investigate and correct compliance issues they have in place to comply with the requirements for Part D plan sponsors. Based on these comments, we are finalizing our proposed provision in part to require POs to adopt a compliance oversight program that requires POs to promptly respond to, investigate and correct potential non-compliance and fraud, waste and abuse.

4. Personnel Qualifications for Staff With Direct Participant Contact (§ 460.64)

Section 460.64 sets forth the personnel qualifications for staff with direct participant contact. In the 2006 final rule (71 FR 71267), we added a requirement at § 460.64(a)(3) that all personnel that have direct participant contact must have a minimum of 1 year of experience with a frail or elderly population. Our rationale was that the PACE population is comprised of frail or elderly individuals who must be cared for by staff with the specific training and experience necessary to understand the complexities and differences in geriatric patients.

However, as we explained in the proposed rule, we are concerned that many POs, especially those in rural settings, may have candidates for PO staff positions who meet all other qualifications for a specific position under § 460.64(a) but do not have 1 year of experience working with the frail or elderly population. We have approved several waivers of this requirement. For example, this situation often arises for positions such as van driver or transportation coordinator. We have received anecdotal reports that some POs encounter van drivers who have many years of relevant experience as school bus drivers but are unable to hire these drivers based on the requirement that staff with direct participant contact have 1 year of experience working with the frail or elderly population. We also have approved this type of waiver request for registered nurses (RNs), social workers, and other direct care providers.

As we stated in the proposed rule, we believe POs should be able to hire individuals who meet all other qualification requirements under § 460.64(a) except for the 1 year of experience requirement under paragraph (a)(3), and provide training to these individuals upon hiring. We explained in the proposed rule that this required training may be provided either through a training entity or directly by the PO. This training must be based on industry standards in order to provide these individuals with the skills necessary to work with the frail or elderly population in PACE. For example, through training, an individual would be taught about the complexities and differences in geriatric patients, and that he or she needs to be gentler, more patient and more observant than with a healthy, younger population. Therefore, we proposed to amend § 460.64(a)(3) to state that a member of the PO's staff (employee or contractor) who has direct participant contact must have 1 year of experience working with a frail or elderly population or, if the individual has less than 1 year of experience but meets all other requirements under paragraph (a) of § 460.64, must receive appropriate training from the PO on working with a frail or elderly population upon hiring. As we noted in the proposed rule, this would afford POs the flexibility to hire an otherwise qualified individual with less than 1 year of experience working with the frail or elderly population and subsequently provide the requisite training.

Current language in § 460.64(a)(4) requires staff with direct participant contact to meet a standardized set of competencies for a specific position established by the PO and approved by CMS before working independently. As we explained in the proposed rule, we continue to believe POs must establish a competency evaluation program for direct participant care staff as required by § 460.71(a)(2) and discussed in the 2006 final rule (71 FR 71267) to ensure that staff have the skills, knowledge and abilities needed to deliver safe care to participants. However, we stated in the proposed rule that we do not believe it is necessary for CMS to approve those competency evaluation programs prior to their use. We expect the PO to use current industry standards. Therefore, we proposed to revise to this paragraph to remove the reference to CMS approval. We also proposed to make technical, non-substantive changes to the language in paragraph (a) by changing the order of the current language in order to make the provision clearer and more concise.

A discussion of the comments we received on the proposed revisions to § 460.64, and our responses to those comments, appears below.

*Comment:* Commenters supported allowing POs to hire individuals with less than 1 year experience with the frail or elderly. Some commenters requested that CMS define ''appropriate training.'' One commenter requested that we require the training to be completed prior to the individual performing any direct care activities.

*Response:* We appreciate the commenters' support and will consider the request to define ''appropriate training'' and when it must be completed in the development of future guidance.

After considering the comments, we are making no changes to our proposal and are finalizing this provision as proposed.

5. Training (§ 460.66)

Section 460.66 requires the PO to provide training for staff members and to develop a specific training program for personal care attendants (PCAs). Paragraph (b) requires the PO to develop a training program for each PCA to establish the individual's competency in furnishing personal care services and specialized skills associated with the specific care needs of individual participants. Paragraph (c) states that PCAs must exhibit competency before performing personal care services independently. We proposed to redesignate § 460.66(b) and (c) to § 460.71, ''Oversight of Direct Participant Care,'' as new paragraphs (c) and (d), respectively, because § 460.71 already includes requirements regarding

training of staff and competency evaluations for employees and contracted staff furnishing care directly to participants. As we explained in the proposed rule, we believe including all of the related requirements in the same section would reduce confusion over applicable requirements. We did not propose any changes to the language in § 460.66(a) but proposed to remove the paragraph designation of paragraph (a).

We did not receive any comments on these proposed changes, and therefore, are finalizing this provision as proposed.

6. Program Integrity (§ 460.68)

Section 460.68 was established to guard against potential conflicts of interest and certain other risks individuals and organizations could present to the integrity of the PACE program. Section 460.68(a) addresses risks presented by a PO employing or contracting with persons with criminal convictions. Section 460.68(a)(1) addresses individuals and organizations that have been excluded from participation in the Medicare or Medicaid programs. Section 460.68(a)(2) addresses individuals and organizations who have been convicted of criminal offenses related to their involvement in Medicaid, Medicare, other health insurance or health care programs, or social service programs under title XX of the Act. Section 460.68(a)(3) currently states that a PO must not employ individuals or contract with organizations or individuals in any capacity where an individual's contact with participants would pose a potential risk because the individual has been convicted of physical, sexual, drug, or alcohol abuse.

As we explained in the proposed rule, we believed the current language in § 460.68(a) may not be tailored to effectively mitigate the risks that employing or contracting with certain individuals and organizations with prior convictions may pose to the PACE program, while still allowing POs to hire and contract with individuals who have had issues in their past that do not pose a risk to the PACE program. Accordingly, we proposed to amend § 460.68(a) by adding clarifying language to current paragraph (a)(3) and by adding two new paragraphs (a)(4) and (a)(5).

We noted in the proposed rule that the current language in § 460.68(a)(3) may have, in some cases, been overbroad so as to impair the PO's ability to hire or contract with appropriate staff. For example, under the current regulation, a PO is precluded from employing an individual with a conviction related to underage drinking, who has not had a conviction in adulthood, who is an otherwise appropriately qualified individual to work in a PO, and who would pose no foreseeable threat to participants. In such cases, persons who have previously misused alcohol and drugs and/or been diagnosed with alcohol use disorder or substance use disorder should not be categorically excluded from serving PACE participants.

In other instances, however, it is possible that an individual's past criminal conviction or convictions related to physical, sexual, drug, or alcohol abuse could provide POs with reason to believe that the individual may pose a threat of harm to participants. For example, there is a foreseeable risk of harm to participants if a PO employs a transportation driver who has a history of multiple Driving Under the Influence (DUI) convictions. We explained that we believed that it is important for POs to consider an individual's past criminal convictions and the potential risk to participants; however, we do not want to limit POs' ability to hire or contract with qualified individuals. This reflects the direction we have taken for long term care facilities (for example, § 483.12(a)(3)(i)), where specific restrictions are focused on individuals that are found guilty of abusing, neglecting or mistreating nursing home residents.

As such, we proposed to amend the language at § 460.68(a)(3) to enable POs to make a determination as to whether an individual's contact with participants would pose a potential risk because the individual has been convicted of one or more criminal offenses related to physical, sexual, drug, or alcohol abuse or use. We noted that POs are still bound by state laws governing the hiring of individuals that provide care and services to the frail elderly in state programs. We also noted that the current language in § 460.68(a)(3), which refers to ''drug, or alcohol abuse'' does not 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. Therefore, we proposed to amend the language to include ''drug, or alcohol abuse or use.''

We stated that although we do not want to foreclose POs from employing or contracting with qualified individuals or organizations that would pose no harm to participants despite past convictions, we proposed to add language in paragraphs (a)(4) and (a)(5), to impose additional limitations on POs employing or contracting with individuals or organizations that may pose a risk to participants. In new paragraph (a)(4), we proposed to add a restriction stating that a PO must not employ individuals or contract with organizations or individuals 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. This language parallels regulatory restrictions applicable to long term care facilities in § 483.12(a)(3)(i). We noted in the proposed rule that we believed these safeguards intended to protect residents in long term care facilities are equally appropriate protections for participants in the PACE program. In paragraph (a)(5), we proposed to add a restriction stating that a PO must not employ individuals or contract with organizations or individuals who have been convicted of any of the crimes listed in section 1128(a) of the Act. These offenses, which are bases for mandatory exclusion from federal health care programs, are: (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. Because we were proposing to add two additional paragraphs to paragraph (a), we proposed to remove the word ''or'' at the end of paragraph (a)(2). We also invited public comment on whether we should extend this provision to restrict hiring those with certain criminal justice histories to also include those with current restraining orders against them.

A discussion of the comments we received on this topic, and our responses to those comments, appears below.

*Comment:* Commenters expressed support for our proposal to allow POs discretion in hiring individuals who have prior convictions but do not pose a current risk to PACE participants. One commenter agreed with our proposal, with the caveat that there must be a high level of training provided to these individuals. One commenter requested we clarify if a PO could consider a conviction from another state.

*Response:* We welcome the commenters' support. We will consider the comments specific to training and convictions from other states in the development of future guidance and are finalizing the provisions as proposed.

*Comment:* In response to our request for comment related to excluding individuals with current restraining orders against them, commenters expressed concern that this would impose a higher standard than what is required for nursing homes.

*Response:* We thank the commenters for responding to our request for comments on a potential restriction for individuals with current restraining orders against them. Many commenters pointed out that this would result in inconsistency with regulatory requirements for long term care facilities. After considering the comments, we are not making any changes to the PACE rules at this time related to individuals with current restraining orders against them.

7. Contracted Services (§ 460.70)

Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act state that, under a PACE program agreement, a PO must furnish items and services to PACE participants directly or under contract with other entities. Accordingly, we require in § 460.70 that all administrative or care-related services, except for emergency services as described in § 460.100, that are not furnished directly by a PO must be obtained through contracts that meet the requirements specified in regulations. In the proposed rule, we solicited comments on whether contracted services authorized by the PO or services operated directly by the PO should comply with the Home and Community-Based Settings (HCBS) regulation at § 441.301(c)(4) when non-institutional settings are used to house and/or provide services to PACE participants, provided they do not conflict with requirements under this section. We noted that the HCBS settings requirements apply broadly to many different Medicaid authorities (including state plan services and waivers, such as sections 1915(c), 1915(i), and 1915(k) of the Act), but currently do not apply to the delivery of services by a PO under sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act. Because POs already support the majority of participants in non-institutional settings, we sought comments on whether or not CMS should apply the requirements to POs. Although we did not propose any changes requiring compliance with § 441.301(c)(4) when non-institutional settings are used to house and/or provide services to PACE participants, we solicited comments on possible proposals to do so in future rulemaking. Changes we considered and on which we solicited comments included:

- Adding a new paragraph § 460.70(b)(1)(iv) stating, a contractor must comply with the HCBS regulation at § 441.301(c)(4) 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 this section.
- Adding a new paragraph § 460.98(b)(4) stating, the PO must comply with the HCBS regulation at § 441.301(c)(4) 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 this section.

A discussion of the comments we received on this topic, and our responses to those comments, appears below.

*Comment:* Most commenters on the topic expressed that the PACE model of care is consistent with the principles and objectives of the HCBS rule, in that care is person-centered and affords individuals choice in where, how and from whom care is given. They stated that under current PACE regulations, POs are already required to ensure an individual's right to privacy, dignity and respect, and freedom from coercion and restraint. A commenter noted that participation in PACE is voluntary, and PACE provides a setting that creates a safe community of individuals to gather for meals and social stimulation to prevent isolation. Commenters expressed concern that a strict application of the HCBS requirement at § 441.301(c)(4) could prevent POs from providing care in the PACE center, where a large proportion of PACE participants access services, when it is often necessary for participants with dementia to attend the PACE center or alternative care setting to ensure their safety. In addition, commenters expressed concern that strict application of the HCBS regulation at § 441.301(c)(4) may impact POs' ability to provide care to PACE participants in ways that have been demonstrated to be successful at delaying or preventing nursing home placement. Commenters noted that it is just as important to allow individuals the right to choose to participate in activities at the PACE center or other congregate locations as it is to protect their right to participate in activities in other community settings. Commenters also expressed concern that application of the HCBS regulation at § 441.301(c)(4) would impact PACE service delivery. Some commenters suggested that application of the HCBS regulation at § 441.301(c)(4) has been inconsistent, and has caused confusion for some providers, and raises safety and access concerns for those caring for people with certain conditions, such as dementia.

*Response:* Based on our review of these comments, we agree with the commenters that many of the existing PACE objectives and requirements are consistent with the requirements of the HCBS regulation at § 441.301(c)(4). We also recognize that some of the principles of the HCBS settings requirements could be adopted in PACE to increase community integration requirements for POs as they facilitate participants' ability to reside independently in the community. Because POs have unique requirements to provide care in both institutional and non-institutional settings, and the role of the PACE center is so fundamental to the provision of PACE services, we believe it is important to be thoughtful before adding or expanding HCBS setting requirements to PACE. We appreciate all of the comments received on this issue, and we plan to use the feedback for consideration in future rulemaking.

*Comment:* While six commenters expressed support for applying the HCBS settings requirements to PACE, they also expressed some concerns that certain elements should or should not apply to PACE. For example, some commenters supported application of the HCBS regulation at § 441.301(c)(4) to all PACE settings except for the PACE center. One commenter suggested a delay in implementation of the HCBS regulation in PACE, or that CMS allow for flexibilities in applying HCBS settings requirements to PACE. Another commenter recommended that alignment of the HCBS regulation at § 441.301(c)(4) to PACE be postponed to a later rulemaking in recognition of the already integrated delivery structure and person-centered approach in PACE. Another commenter that supported the application of the HCBS settings requirements for non-intuitional settings in PACE stated that PACE participants living in settings such as assisted living and residential care facilities should be able to move into these types of setting. One commenter expressed concern that the eviction protection in the HCBS settings rules may conflict with the PACE involuntary disenrollment regulations. Some commenters supported application of the HCBS regulation at § 441.301(c)(4) to PACE, but stated that implementation should not have the unintended consequence of preventing POs or their contractors from providing housing or services that enable people to live independently in their homes and communities

(including supports for family caregivers).

*Response:* We appreciate the detailed comments about how the HCBS regulation at § 441.301(c)(4) should or should not apply in PACE, and will continue to evaluate the appropriateness of the application of the HCBS regulation in PACE and use this feedback for consideration in future rulemaking.

*Comment:* Some commenters stated that the HCBS settings requirements should be expanded to cover existing PACE programs, and that any HCBS provider must be held to the same standards and requirements. They expressed that even though PACE services often are provided at a specific PACE center, the availability of services at the center should not have the effect of isolating participants from the broader community. Some commenters expressed there is no reason why the HCBS settings requirements should not apply to PACE, since PACE, like other HCBS options and waivers, is designed to provide a non-institutional alternative for persons with LTSS needs. Therefore, they stated that any HCBS provided by POs, either directly or through contractual arrangements, should be subject to the HCBS regulation at § 441.301(c)(4). Several of the commenters recommended that CMS, in addition to incorporating the HCBS settings requirements in § 441.301(c)(4), should incorporate paragraph (c)(5). Paragraph (c)(4) sets standards for HCBS settings, and paragraph (c)(5) describes settings that cannot be considered home and community-based. Those commenters stated that POs and their contractors should comply with both of these paragraphs.

*Response:* While we believe that many of the existing PACE objectives and requirements are consistent with the requirements of the HCBS Settings final rule at 42 CFR part 441, we recognize that some of the principles of that rule could be adapted in PACE to increase community integration requirements for POs as they facilitate participants' ability to reside independently in the community. Because PACE differs from every other HCBS program in that POs are required to provide care in institutional and non-institutional settings and the PACE center is so fundamental to the provision of services, we believe it is important that we carefully and thoughtfully weigh many factors before adding or expanding HCBS setting requirements to PACE. As a result, we are not incorporating any HCBS settings requirements into PACE at this time. We appreciate all of the comments received on this issue, and plan to use the feedback for consideration in future rulemaking.

In addition to soliciting comments on the HCBS settings requirements, we proposed several revisions concerning contracts with entities that furnish administrative or care-related services. Section 460.70(d)(5) specifies the required terms for contracts with entities that furnish administrative or care-related services. Sections 460.70(d)(5)(vi) through (ix) address additional contract requirements where the PO chooses to contract with individuals as IDT members or key administrative staff. We explained in the proposed rule that, although the current provisions do not explicitly reference those individuals, this was our intent when we adopted the requirements in the 2002 IFC (67 FR 61498, 61505), and when we addressed these requirements in the 2006 final rule (71 FR 71270, 71335). We noted that this is also how we have interpreted the regulation in practice, however, we understand it has caused confusion for POs. To make the regulation clearer and reduce confusion, we proposed to add a new paragraph (d)(6) under which we proposed to redesignate § 460.70(d)(5)(vi) through (ix) as § 460.70(d)(6)(i) through (iv) and state that these contract requirements apply to individuals providing contracted services to the IDT or performing the duties of the program director or medical director. We also proposed to make a technical change to the language in former § 460.70(d)(5)(vii) (proposed § 460.70(d)(6)(ii)) to change ''meeting'' to ''meetings.''

We proposed to make a technical change to § 460.70(e)(2) to change ''PACE Center'' to ''PACE center'' consistent with the definition in § 460.6, and other references throughout the regulation. We proposed to revise § 460.70(e)(2) to correct the reference contained in that section by changing § 460.98(d) to be § 460.98(c).

A discussion of the comments we received on the proposed changes to § 460.70, and our responses to those comments, appear below.

*Comment:* Some commenters requested that we expand § 460.70, the existing regulation that requires POs to provide services directly or under contract with other entities, to allow the use of non-contracted providers.

*Response:* Under the scope of benefits described in sections 1894(b)(1) and 1934(b)(1) of the Act, a PO may enter into written contracts with outside entities to furnish services to participants that are not provided directly by the PO. Consequently, we require in § 460.70 that all services, except for emergency services as described in § 460.100, not furnished directly by a PO must be obtained through contracts which meet the requirements specified in regulations.

*Comment:* One commenter requested that we provide an exception to the contract requirements in § 460.70 for administrative or care-related services that are provided by a PO's parent organization.

*Response:* We would not grant such an exception as we expect the PO to have contractual arrangements for accountability purposes with all entities that furnish services not directly furnished by the PO (except emergency services), including the PO's parent organization. As the PO's parent organization can change, for example, when a CHOW occurs, it is essential that a contract is in place to show any existing relationship and services provided by the parent organization.

Because the statute requires POs to provide PACE services directly or through contracts with other entities, we do not believe we can expand § 460.70 to allow the use of non-contracted providers in PACE as requested by the commenters. After considering the comments, we are finalizing the changes to § 460.70 as proposed.

8. Oversight of Direct Participant Care (§ 460.71)

Section 460.71 identifies PO oversight requirements for employees and contracted staff with direct patient care responsibilities. Paragraph (a) requires the PO to ensure that all employees and contracted staff furnishing care directly to participants demonstrate the skills necessary for performance of their position, and further requires, under paragraph (a)(1), that the PO provide an orientation to all employees and contracted staff. Paragraph (b) requires the PO to develop a program to ensure that all staff furnishing direct participant care services meet certain requirements, including, under paragraph (b)(4) that they are free of communicable diseases and are up to date with immunizations before performing direct patient care.

We proposed to make some technical, non-substantive changes to paragraph (a)(1) that would make the provision more concise. We also proposed to amend paragraph (b)(4). As we explained in the proposed rule, our intent when we amended § 460.71 in the 2006 final rule was to reflect our current policy described in § 460.64(a)(5), which states that PACE staff (employees or contractors) who have direct

participant contact must be medically cleared for communicable diseases and have all immunizations up-to-date before engaging in direct participant contact (71 FR 71273). We noted that § 460.71(b)(4) was not amended in a consistent manner, which we understood caused confusion among POs about whether to attach the same meaning to ''medically cleared for communicable diseases'' and ''free of communicable diseases.'' Therefore, we proposed to amend § 460.71(b)(4) by referencing the language previously added to § 460.64(a)(5) so that both sections would be consistent and contain the same language.

As noted previously in our discussion of proposed changes to § 460.66, we proposed to move paragraphs (b) and (c) of § 460.66 related to personal care services furnished by PCAs to § 460.71(c) and (d), respectively.

A discussion of the comment we received on this topic, and our response to that comment, appears below.

*Comment:* One commenter stated that the proposed rule does not specify a minimum curriculum or minimum training standards for PCAs and suggested that the PACE manual define the minimal competencies that PCAs are expected to demonstrate before performing personal care tasks independently.

*Response:* As we have previously stated in our discussion on personnel qualifications for staff with direct participant contact (see subpart E.4. (Personnel Qualifications for Staff with Direct Participant Contact (§ 460.64)), it is our expectation that POs follow industry standards with respect to the skills required for working with the frail or elderly population in PACE. Therefore, we do not believe it is necessary at this time to specify minimum training standards or competencies for PCAs.

9. Physical Environment (§ 460.72)

Section 460.72 of the PACE regulations addresses requirements for the physical environment of the PACE center, including those pertaining to space and equipment, fire safety, and building safety. In the proposed rule, we noted that CMS had published in the December 27, 2013 **Federal Register** a separate proposed rule that would affect the PACE requirements for emergency preparedness that, at the time, were included in § 460.72 (see 78 FR 79802). This proposal has now been finalized. Specifically, on September 16, 2016, we published in the **Federal Register** a final rule titled ''Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers,'' which revised the PACE requirements at § 460.72 and added a new § 460.84. The final rule (81 FR 63860) established national emergency preparedness requirements for 17 types of Medicare- and Medicaid-participating providers and suppliers, including POs, to ensure that they adequately plan for both natural and man-made disasters, and coordinate with federal, state, tribal, regional, and local emergency preparedness systems. For a complete discussion of the PACE emergency preparedness revisions, see the September 16, 2016 final rule (81 FR 63904 through 63906).

10. Marketing (§ 460.82)

Section 460.82 addresses requirements governing the marketing activities of POs. Section 460.82 provides special language requirements, and paragraph (c)(1) states that a PO must furnish printed marketing materials to prospective and current participants in English and in any other principal languages of the community. We proposed to further clarify this requirement by defining what we mean by ''principal languages of the community.'' We noted in the proposed rule that, as we stated in the 2006 final rule (71 FR 71279), we believed the determination of a principal language of the community is a state determination. However, we recognized that not all states have an established standard for when a language is considered to be a principal language of the community (in other words, a language threshold). Where a state has not established such a standard, we proposed the following standard would be applied—a principal language of the community would be any language spoken in the home by at least 5 percent of the individuals in the PO's service area.

As we explained in the proposed rule, we referred to any language spoken ''in the home'' because U.S. Census data identifies the principal language as the primary language spoken in the home. We noted that we established a similar 5 percent language threshold for marketing materials in the Medicare Advantage program (§ 422.2264(e)), and we believed this threshold is also appropriate for PACE. Moreover, we stated in the proposed rule, we strive to create harmony across program requirements when feasible. This reduces complexity for those organizations that operate multiple CMS programs. We explained that, currently, in the MA program, we determine which MA organizations must provide translated marketing materials by using the U.S. Census Bureau's American Community Survey (ACS) data, and we then communicate that information to plans via HPMS. We noted that we did not propose to replace any state-based language thresholds; rather the goal was to provide a standard in instances where a state standard does not exist. Additionally, we noted in the proposed rule, we would not preclude POs from producing materials in alternative languages when those languages are spoken by less than 5 percent of the individuals in the PO's service area; rather we aimed to set a more clear standard for when furnishing such materials is a requirement.

We did not receive any comments on our proposal to use the same approach to the language threshold determination as we do in the MA program, and therefore, we are finalizing the provision as proposed.

Paragraph (e) pertains to prohibited marketing practices and places certain restrictions on PO employees and agents. Paragraph (e)(3) states that gifts or payments to induce enrollment are prohibited. As we stated in the proposed rule (81 FR 54680) and the 2006 final rule (71 FR 71279), this provision does not prevent a PO from offering gifts of a nominal value. For example, as we explained in the proposed rule and 2006 final rule, offering gifts to potential enrollees who attend a marketing presentation is permitted as long as these gifts are of a nominal amount and are provided whether or not the individual enrolls in the PACE program. The gift cannot be a cash gift or be readily converted into cash regardless of the amount. To ensure that our regulations reflect this distinction, we proposed to amend paragraph (e)(3) to specify that gifts or payments to induce enrollment are prohibited, unless the gifts are of nominal value as defined in CMS guidance, are offered to all potential enrollees without regard to whether they enroll in the PACE program, and are not in the form of cash or other monetary rebates. We stated in the proposed rule that CMS currently defines ''nominal value'' in section 30.10 of the PACE Marketing Guidelines (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pace111c03.pdf*) to mean an item worth $15 or less, based on the retail value of the item, which is consistent with the values in the marketing guidelines under the Medicare Advantage and Medicare Part D programs. We noted in the proposed rule that we believed the revision to paragraph (e)(3) would preserve our goal of ensuring that current and potential PACE participants and their families or

guardians elect PACE based on the merits of the program versus the enticement of a gift, while clarifying that POs have the ability to offer prospective participants a small gift such as a pen with the organization's name and contact information without the concern of violating the PACE marketing regulations. We stated that similar flexibility has been permitted under both the MA and Part D programs for several years with no notable adverse impact to participants. As such, we explained in the proposed rule, the PACE program will continue to look to these two programs to define the monetary value that constitutes a nominal gift. In addition, and consistent with the MA and Part D programs, we stated in the proposed rule that the PACE regulatory definition of a nominal gift would exclude any gifts in the form of cash or monetary rebates.

Section 460.82(e)(4) prohibits contracting outreach efforts to individuals or organizations whose sole responsibility involves direct contact with the elderly to solicit enrollment. Due to the particular nature of the PACE program and the PACE population, we stated in the proposed rule that we believed it is in the best interest of the program to only permit POs to market their programs through their own employees. Therefore, we proposed amendments to this section to specifically prohibit POs from using non-employed agents/brokers, including contracted entities, to market PACE programs.

As we explained in the proposed rule, the decision to enroll in a PACE program is significantly different from the decision to enroll into other Medicare or Medicaid managed care programs because PACE participants must agree to receive all medical care (as well as other services) from the PO into which they enroll. This may mean PACE participants must give up longstanding relationships with health care providers, as well as become liable for the costs of any unauthorized services. We noted that this is an important distinction that non-employed agents and brokers may overlook when they market PACE programs to potential participants. Agents and brokers that do not work for POs often sell other products, such as Medicare Advantage and Medicare PDP products. These products are significantly different from PACE in many respects, including the services that are covered, the ways in which participants receive the services, and the enrollment requirements for participants.

In the proposed rule, we expressed concern that these substantial differences, combined with the typical low enrollment numbers associated with the PACE program, make it difficult for agents and brokers that are not employed by POs to fully understand and explain the PACE program to potential participants. We emphasized that our concern was less about false marketing (which connotes a malicious action) and more about enrollment numbers not becoming the primary motivation when marketing PACE. An independent third party would likely not have the opportunity to develop the necessary expertise to act as agents employed by a PO. We stated we believed employees of the PO would be the best equipped to provide potential participants and their caregivers with accurate information about the PO, the services it provides and the ramifications of receiving services not approved by the PO's IDT. We noted this is especially important given the vulnerable nature of the PACE population, which is elderly and frail and often has more complex health care needs than Medicare or Medicaid managed care populations, for which the use of non-employed agents and brokers for marketing may be more appropriate.

As we discussed in the proposed rule, we believed that only permitting POs to use employees for marketing activities would help ensure potential PACE participants fully understand the program, the rules, how to access services, and the ramifications of not accessing services through the PO. Accordingly, we proposed to amend § 460.82(e) to remove the term ''agents'' and simplify the language. The revised provision would preclude POs from using certain prohibited marketing practices. In conjunction with that revision, we proposed to amend paragraph (e)(4) to prohibit marketing by any individuals other than the employees of the PO. We noted that some POs may have existing arrangements with independent agents and brokers and that, as with other functions, POs may delegate such responsibilities to an outside entity. We solicited comments as to whether CMS' proposed prohibition on the use of independent agents and brokers is appropriate. We stated that if commenters believed that this prohibition is not appropriate, they should provide specific reasons for allowing their use, descriptions of how POs contemplate using agents and brokers, and the protections POs have in place to ensure accurate information is provided to potential PACE participants. We describe the comments we received on this proposal and our responses at the end of this section.

Section 460.82(e)(5) prohibits unsolicited door-to-door marketing. We proposed to add language to § 460.82(e)(5) specifying that any other unsolicited means of direct contact, including calling or emailing a potential or current participant without the individual initiating contact, is a prohibited marketing practice under PACE. We explained that unsolicited contact, for example, through telephone (also known as ''cold calling'') or email, is similar to, and generally as prevalent if not more prevalent, than door-to-door marketing, which is already expressly prohibited under § 460.82(e)(5). We stated the purpose of this addition is to clarify that unsolicited means of direct contact through telephone and email are not allowed under PACE. Although we declined in the 2006 final rule to expand this prohibition beyond door-to-door solicitation, we stated we would continue to monitor marketing practices by POs and would propose additional safeguards as appropriate (71 FR 71279). We explained in the proposed rule that based on the vulnerability of the population served by the PACE program and the increase in health care fraud we have seen since 2006, we believed a prohibition on other unsolicited means of direct contact is appropriate for PACE. Moreover, we noted, such a prohibition is consistent with our marketing requirements for MA organizations (§ 422.2268(d)) and PDP sponsors (§ 423.2268(d)).

We also proposed to remove § 460.82(f), which requires that POs establish, implement, and maintain a documented marketing plan with measurable enrollment objectives and a system for tracking its effectiveness. We explained that based on the insight we have gained through years of oversight responsibility for the PACE program, we believed the requirement for a marketing plan is redundant. We noted in the proposed rule that we believed that the pertinent information captured in the plan is attainable through other account management activities. For example, POs convey marketing strategy in regularly scheduled meetings with their CMS Account Managers. We explained that the CMS Account Managers are also made aware of marketing materials and messages, as well as the intended audience for such materials and messages, through the marketing submission and review process. In addition, CMS has a separate method for tracking enrollment data.

A discussion of the public comments we received on our marketing proposals, and our responses to those comments, appears below.

*Comment:* Commenters expressed concerns that the proposed simplified language under § 460.82(e)(4) could be construed as also prohibiting states and advocates from educating potential participants about PACE. Several commenters expressed that POs should maintain the flexibility of using contracted entities to assist them with marketing activities. Two commenters expressed agreement with our proposal to restrict marketing to employees of the PO. One such commenter expressed concern with fraud, confusion, and abuse associated with marketing by non-employees, while the other commenter did not provide a reason for agreeing with the proposed restriction.

*Response:* As a result of the comments, we note that the proposal to restrict marketing to employees of the PO was not intended to preclude states and advocacy groups from discussing PACE with potential participants. To clarify this position, we are revising § 460.82(e)(4) to prohibit marketing by any individual or entity that is directly or indirectly compensated by the PO based on activities or outcomes, as opposed to marketing by any individuals other than employees of the PO. We are also revising our proposal to differentiate between those entities which receive some level of compensation from the PO based on activities or outcomes in marketing PACE on behalf of the PO, and those who are educating potential participants on a host of potential healthcare choices, but are not compensated by the PO based on any activity or outcome, such as State Health Insurance Assistance Programs (SHIPs) and other advocates in the community.

Additionally, based on the majority of comments received, we believe it is best to be less prescriptive with regard to who can and cannot engage in marketing activities under PACE and to instead revise our proposal to address the root concerns of non-PO staff marketing PACE, such as a lack of understanding of the nuances of the PACE program and/or PO that could lead to an enrollment decision that is contrary to the best interest of the potential participant. Specifically, we are revising § 460.82(e)(4) to allow marketing by an individual or entity that is directly or indirectly compensated by the PO based on activities or outcomes if the individual or entity has been appropriately trained in PACE program requirements, including but not limited to 42 CFR part 460, subparts G and I of this part, addressing participant rights and participant enrollment and disenrollment, respectively. We are also adding provisions in § 460.82(e)(4)(i) and (ii) that state POs are responsible for the activities of contracted individuals or entities who market on their behalf, and that POs that choose to use contracted individuals or entities for marketing purposes must develop a method to document training has been provided, respectively.

By outlining expectations for the appropriate training combined with reiterating that the PO is responsible for marketing activities conducted by others on its behalf, we believe we are providing additional flexibility to POs while still safeguarding potential and current PACE participants. Moreover, we believe that this change will address the concerns of fraud, confusion, and abuse expressed by the commenter who was in favor of the proposed agent marketing prohibition.

We are finalizing the other proposed changes to the marketing requirements—§§ 460.82(c)(1), 460.82(e) introductory text, 460.82(e)(3), and 460.82(e)(5)—as outlined in the proposed rule.

*G. Subpart F—PACE Services*

1. Service Delivery (§ 460.98)

Section 460.98 addresses service delivery under PACE. We proposed to make a technical change to the heading of § 460.98(d) to replace ''PACE Center'' with ''PACE center'' for consistency with other references in § 460.98 and throughout part 460. Likewise, in paragraph (d)(3) we proposed to replace ''Pace center'' with ''PACE center'' for the same reason.

We also solicited public comments on potential changes to our PACE center requirements, which originated from the PACE Protocol. As defined in § 460.6, a PACE center is a facility which includes a primary care clinic, areas for therapeutic recreation, restorative therapies, socialization, personal care, and dining, and which serves as the focal point for coordination and provision of most PACE services. Under § 460.98(b)(2), PACE services must be furnished in at least the PACE center, the home and inpatient facilities, and under § 460.98(c), certain minimum services must be furnished at each PACE center. Section 460.98(d) requires a PO to operate at least one PACE center either in, or contiguous to, its defined service area with sufficient capacity to allow routine attendance by participants. A PO must ensure accessible and adequate services to meet the needs of its participants and, if necessary, must increase the number of PACE centers, staff, or other PACE services. If a PO operates more than one center, each PACE center must offer the full range of services and have sufficient staff to meet the needs of participants.

As we explained in the proposed rule (81 FR 54681) and the 2006 final rule (71 FR 71283), we believe the success of the PACE delivery model has been predicated on the combination of the IDT assessment, care planning, and the PACE center. The PACE center requirement established in the original PACE Protocol provides a point of service where the primary care clinic is located, where services are provided, and socialization occurs with staff that is consistent and familiar. The IDT not only works from the PACE center, it also provides the majority of services to participants at the PACE center, where most participants come on a regular basis to receive the majority of their care. Attendance at the center has been considered an important aspect of the PACE model of care, which helps to differentiate it from home health care or institutional care. We noted that more recently, CMS has allowed participants to receive services at alternative care settings. However, those services are meant to supplement, not replace, the services that the PACE center must furnish.

We further explained in the proposed rule that, over the years, we have received a number of requests to provide greater flexibility with respect to the PACE center operation and service requirements. We have heard concerns that the development costs and the length of time required to establish a PACE center can be significant and inhibit expansion of existing programs. To better understand the issues facing POs, in the proposed rule, we solicited public comment on ways to revise the current regulatory requirements to allow greater flexibility with regard to the 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 of care for this population. We stated that we will use public comments to inform future PACE rulemaking concerning how to allow greater flexibility with regard to the settings in which IDT members provide PACE services.

A discussion of the public comments we received on this topic, and our responses to those comments, appears below.

*Comment:* Commenters generally supported potentially allowing POs

greater flexibility to utilize alternative care settings (for example, adult day care centers, senior centers, or activity areas in residential communities). One commenter recommended that CMS modify PACE requirements consistent with certain principles including, for example, that PACE participants must be assigned to a PACE IDT, but the IDT does not have to be assigned to a PACE center. Many commenters stated that the ability to deliver care in alternative care settings would provide POs more flexibility in responding to participants' needs and preferences, and promote PACE growth and expansion in ways that are not constrained by POs' ability to construct new PACE centers. However, other commenters expressed concern regarding the potential for significant movement away from delivering care at the PACE center, which is considered the essence of the PACE model of care, toward increased reliance on providing care in settings outside the PACE center. One commenter suggested that increased flexibility in service delivery settings for PACE may result in the program becoming more like network-based Medicare and Medicaid managed care programs. Another commenter suggested that providing more flexibility to POs with respect to service delivery settings could result in an ''unlevel playing field'' between POs and other health plans serving similar populations. Therefore, this commenter recommended that as CMS works to introduce flexibilities around the PACE program, it should align standards and requirements for POs with those for other Medicare and Medicaid managed care plans where appropriate.

Commenters also suggested that CMS would need to consider and provide an opportunity for comment on the potential need for alignment across CMS programs of various operational and program requirements.

*Response:* We appreciate the thoughtful comments and recommendations provided by commenters. The feedback will help inform future PACE rulemaking.

*Comment:* Many commenters supported testing use of the PACE model of care for new populations under section 1115A of the Act, which was afforded by the PACE Innovation Act of 2015 (PIA), including testing the PACE model of care for individuals younger than 55 with disabilities, who are currently ineligible for PACE because of their age. Some commenters expressed concern regarding the opportunity to test expansion of PACE under this authority. For example, one commenter stated that any future model test under section 1115A of the Act, as amended by the PIA, to serve individuals with psychiatric disabilities should be governed by the January 16, 2014 Medicaid final rule [7] that establishes the requirements and limits applicable to Medicaid HCBS in order to restrict the use of a PACE center as a location for the delivery of services to this population. Another commenter urged us to use the authority provided by the PIA to find affordable ways to extend the PACE model of care to older adults with Medicare who need LTSS but are not eligible for Medicaid. Finally, the Medicare Payment Advisory Commission (MedPAC) urged us to consider changes to the PACE rate setting and risk adjustment methodologies to increase the accuracy of payments under any model test.

*Response:* We appreciate the recommendations on potential tests of the PACE model of care under the authority of section 1115A of the Act, as amended by the PIA. We will continue to consider future opportunities to conduct model tests under this authority. However, our focus currently is on developing models through which we would directly contract with a range of Medicare providers and suppliers, and these providers and suppliers would agree to be accountable for cost and quality in providing care to a defined beneficiary population. We are working to ensure these potential models would provide opportunities to test innovative ways to serve people of all ages who have complex chronic conditions and/or functional impairments, building on what has worked well with the PACE clinical approach. Comments on the PIA are beyond the scope of this rule, as this rule pertains to the existing PACE program, and any potential waivers of existing PACE regulations, changes to payment methodology or modifications to eligibility criteria for a model test under section 1115A of the Act as amended by the PIA would be addressed as appropriate for each model. However, we will take the commenters' input, as well as the comments received in response to the PACE Innovation Act Request for Information [8] issued December 23, 2016, into account as we develop future model tests.

[7] *https://www.federalregister.gov/documents/2014/01/16/2014-00487/medicaid-program-state-plan-home-and-community-based-services-5-year-period-for-waivers-provider.*

[8] See *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/PACE/PACE-Innovation-Act.html.*

*Comment:* In response to a proposed revision to the IDT role of the primary care provider, commenters suggested a corresponding revision to § 460.98(c)(1) to state that primary care services furnished at the PACE center may be provided by a physician, nurse practitioner or physician assistant.

*Response:* Section 460.98(c)(1) currently refers to primary care services as including physician and nursing services. However, as discussed in section III.G.3. of this final rule, we proposed and are finalizing changes to § 460.102(b) and (c) to permit primary medical care to be furnished by a primary care provider, meaning 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). We appreciate the suggested revision and agree that it would help ensure consistency between the two sections of the regulation. Therefore, we will revise § 460.98(c)(1) to refer to the minimum services furnished at each PACE center as including ''primary care, including services furnished by a primary care provider as defined in § 460.102(c) and nursing services.'' This change will recognize that primary care can be provided not only by physicians and nurses, but also by other types of primary care providers, as defined in § 460.102(c).

*Comment:* One commenter requested that we provide more detailed guidance with respect to alternative care settings in PACE.

*Response:* We did not propose any changes regarding alternative care settings, so we consider this topic to be beyond the scope of this rule. We direct the commenter to the guidance we issued on alternative care settings in PACE. (See the June 30, 2016 HPMS memorandum, Clarification on the Requirements for Alternative Care Settings in the PACE Program.)

2. Emergency Care (§ 460.100)

Section 460.100 addresses emergency care under PACE. We proposed to make a technical revision to § 460.100(e)(3)(i) by replacing references to ''POs'' and ''PO'' with references to ''PACE organizations'' and ''PACE organization,'' respectively, to make the language consistent throughout § 460.100 and with other references in part 460.

We did not receive any comments on this proposal, and therefore, we are finalizing the change as proposed.

3. Interdisciplinary Team (§ 460.102)

Section 460.102 sets forth the requirements for an IDT, which are based on provisions in Part IV, section B of the PACE Protocol (64 FR 66248). As we have stated previously in preambles to rules and subregulatory guidance (*http://cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pace111c08.pdf*), we believe a well-functioning IDT is critical to the success of the PACE program because the team is instrumental in controlling the delivery, quality, and continuity of care. Further, members of the IDT should be knowledgeable about the overall needs of the participants, not just the needs that relate to their individual disciplines (64 FR 66248; 71 FR 71285; 81 FR 54682). Section 460.102(a)(1) requires that the PO establish an IDT at each PACE center to comprehensively assess and meet the individual needs of each participant. Section 460.102(b) specifies the composition of the team and provides that it be comprised of at least the 11 members listed in the section.

Under sections 1894(f)(2)(B)(iii) and 1934(f)(2)(B)(iii) of the Act, the IDT approach to care management and service delivery is a requirement that cannot be waived. However, we explained in the proposed rule that we understood there may be circumstances when it would be difficult for a PO to have a separate individual fill each of the 11 IDT roles, which may be an obstacle for the expansion of the PACE program, especially in rural areas. To provide greater flexibility for POs, we proposed that a PO be permitted to have one individual fulfill two separate roles on an IDT when the individual meets applicable state licensure requirements and is qualified to fill each role and able to provide appropriate care to meet the participant's needs. For example, we noted, a registered nurse cannot fill the role of a Master's-level social worker unless the registered nurse also has a master's degree in social work. Under § 460.190 and § 460.192, CMS and the SAA monitor POs during the trial period and perform ongoing monitoring after the trial period to ensure that POs are in compliance with all PACE requirements. We explained in the proposed rule that these monitoring activities will serve as a safeguard to help ensure there is no negative impact to the quality of care being provided. During these reviews, CMS and the SAA can confirm that when an IDT member is serving in two IDT roles, participants' needs are still being met. As such, we proposed to revise paragraph (a)(1) to state that the IDT must be composed of members that fill the roles described in paragraph (b). We also proposed to revise paragraph (b) to state the IDT must be composed of members qualified to fill, at minimum, the following roles, in accordance with CMS guidelines. We stated that we will publish the IDT guidelines in HPMS following publication of the final rule. We noted that paragraph (b) would also state that one individual may fill two separate roles on the IDT where the individual meets applicable state licensure requirements and is qualified to fill the two roles and able to provide appropriate care to meet the needs of participants.

A discussion of the public comments we received on our proposal regarding IDT roles, and our response to those comments, appears below.

*Comment:* Commenters supported the proposal to allow one individual to fill two separate roles on the IDT where the individual has the appropriate licenses and qualifications for both roles.

*Response:* We appreciate the support for this proposal and will finalize the revisions as proposed. As noted previously, we will publish IDT guidelines in HPMS following the publication of the final rule.

Section 460.102(b)(1) currently provides that the IDT must include a primary care physician, and § 460.102(c) requires that primary medical care be furnished by a PACE primary care physician who is responsible for managing a participant's medical situations and overseeing a participant's use of medical specialists and inpatient care. As we stated in the proposed rule, we are aware that changes in the practice of medicine and state licensing laws have expanded the practice of non-physician practitioners (for example, nurse practitioners), such that these practitioners in many cases are able to fulfill the role served by the primary care physician. Thus, including those individuals on the IDT in the role of the primary care provider may prove to be more operationally feasible and cost-effective, particularly in rural areas or areas where labor costs may be high. We noted that we have approved requests by POs to waive the requirement at § 460.102(b)(1) and (c) so that primary medical care can be furnished by someone other than a primary care physician on the IDT, thus allowing POs to deliver care through a non-physician primary care provider (such as a nurse practitioner or physician assistant) or a community-based physician. We stated that we have typically granted such waivers, and we have not encountered any issues or concerns with the quality of care provided by non-physician primary care providers or community-based physicians acting in this capacity on behalf of and working collaboratively with the PACE primary care physician or medical director.

As we explained in the proposed rule (81 FR 54682), 1999 IFC (64 FR 66248), and the 2006 final rule (71 FR 71285), the role of primary care physician on the IDT was based on the PACE Protocol and codified in regulation. In the 2006 final rule, we explained that we considered expanding this role to include nurse practitioners but decided to retain the PACE Protocol requirement. We noted our view at the time that it would be acceptable to include a nurse practitioner on the IDT, but it should be in addition to rather than instead of a primary care physician. We also stated in the 2006 final rule that such a change should be included in a proposed rule in order to allow for public comment on this issue; and in the meantime we would continue to assess the appropriateness of allowing nurse practitioners to assume the role of the primary care physician consistent with state licensure requirements for nurse practitioners (71 FR 71285).

As discussed in the proposed rule, the PACE program agreement has replaced the PACE Protocol. We noted that, like certain other requirements that were based on the PACE Protocol, we believed the composition of the IDT needs to change to reflect evolving medical practices and technologies. We stated that we believed it is appropriate to expand the primary care physician role on the IDT to include certain other primary care providers. Accordingly, we proposed 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. Further, we proposed 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). We also proposed to revise § 460.102(c)(2) to refer to primary care provider rather than primary care physician. We stated that these changes would allow all POs to furnish primary care through these other types of providers, thereby reducing burden on the POs without compromising care.

For physician assistants and nurse practitioners, we proposed to add language in paragraphs (c)(1)(iii) and (iv) to require that they 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. We noted that, with increasing shortages of primary care providers across the country, we believed affording POs the flexibility to involve other non-physician practitioners practicing collaboratively with the PACE primary care physicians would enable the POs to accommodate more participants and expand their programs, without comprising quality of care.

We proposed redesignating the current language in paragraph (e) as paragraph (f) and, in a new paragraph (e), we proposed to add language that references the requirements in § 460.71, which sets forth guidelines for the oversight of employees and contracted staff that have direct patient contact. We explained that referencing § 460.71 should make it clear to POs that they must ensure that all members of the IDT demonstrate the skills necessary for the performance of their positions as required under § 460.71. Additionally, we noted, this will require the PO to confirm that all members of the IDT comply with state certification or licensure requirements for direct patient care in their respective settings. The PO and its medical director are responsible for the oversight of all care provided to PACE participants.

A discussion of the public comments we received on our proposal regarding primary care providers on the IDT, and our responses to those comments, appears below.

*Comment:* Commenters strongly supported revising the regulations to require a primary care provider to serve on the IDT instead of requiring a primary care physician. This would permit nurse practitioners, physician assistants, and community-based physicians to fill this role. Some commenters suggested what they believed to be necessary corresponding revisions to other sections of the PACE regulations related to the settings in which a primary care provider provides services. Specifically, commenters suggested that we clarify in § 460.98 whether a primary care provider may provide services in a community-based setting. Similarly, the commenters requested a clarifying revision to § 460.98(c)(1) regarding the primary care services furnished at the PACE center. A few commenters recommended that a nurse practitioner be listed as a provider who can serve as the medical director for a PO. Commenters also questioned if the PO's medical director must be a medical doctor.

*Response:* We appreciate the support for the proposed revisions to § 460.102 regarding the primary care provider and will finalize that change to the regulation as proposed. Regarding the suggestion that we clarify whether a primary care provider may provide services in a community-based setting, we do not believe that a clarification is necessary in light of the removal of the ''primarily served'' requirement discussed below. We do appreciate the suggested clarifying revision to § 460.98(c)(1) to ensure consistency between the two sections of the regulation. As discussed in section III.G.1. of this final rule, we are revising § 460.98(c)(1) to refer to ''primary care, including services furnished by a primary care provider as defined in § 460.102(c) and nursing services''. Regarding the role of the PACE medical director and which disciplines can serve in this capacity, we initially proposed regulation text at § 460.60(b) that would require a PO to employ or contract with a physician in accordance with § 460.70, to serve as its medical director responsible for the delivery of participant care, for clinical outcomes, and for the implementation, as well as oversight, of the quality improvement program. However, at this time, we are not finalizing the change to specify that a physician must as serve as the medical director. We intend to address questions regarding the PACE medical director role in future guidance or rulemaking.

Currently, § 460.102(d)(3) states that the members of the IDT must serve primarily PACE participants. The ''primarily served'' requirement was part of the original PACE Protocol (64 FR 66249). However, section 903 of BIPA authorizes the Secretary to modify or waive such provisions in a manner that responds promptly to the needs of PACE programs relating to areas of employment and the use of community-based primary care physicians. We proposed to revise § 460.102(c)(1) to allow community-based physicians to fill the role of primary care provider on the IDT. As we explained in the proposed rule, community-based physicians are different from the PACE primary care physician. The PACE primary care physician works for the PO and is responsible for all PACE participants within the PO. The community-based physician generally works in a different practice, outside of the PO, but may also contract with the PO in order to work with select PACE participants who prefer to continue to receive their primary care services from their community-based physician. Community-based physicians usually provide care for the patients in community settings, such as outpatient clinics, and patients in those community settings often become PACE participants. Newly enrolled PACE participants often request to continue receiving care from their community-based physician. We noted in the proposed rule that we wanted to allow this flexibility for PACE participants because we believed it supports the continuity of care for participants. Therefore, we proposed to amend § 460.102(d)(3) to allow flexibility with respect to community-based physicians by excluding them from the requirement that they serve primarily PACE participants. As proposed, community-based physicians would be able to continue working in their community settings while contracting with the POs to provide PACE services. We also stated in the proposed rule that, in combination with the revision to paragraph (b)(1), this would effectively be a global waiver of the IDT member and ''primarily served'' requirements for community-based primary care physicians.

A discussion of the public comments we received on our proposal regarding the ''primarily served'' requirement, and our responses to those comments, appears below.

*Comment:* Most commenters concurred with eliminating the ''primarily served'' requirement for community-based physicians and suggested that this be extended to other types of community-based providers and possibly all members of the IDT.

*Response:* We thank the commenters for their support for this change. In response to these comments, as well as in response to comments we received on the alternative IDT proposals that are discussed next, we are finalizing changes to the ''primarily served'' requirement that renders our proposal on community-based physicians unnecessary. Changes to the ''primarily served'' requirement are further discussed below.

In the proposed rule, we also considered two alternative possibilities for revising parts of § 460.102 to provide greater flexibility to POs without compromising quality of care. In the first alternative, we considered deleting the requirements in § 460.102(b) related to the composition of the IDT. As noted previously, under sections 1894(f)(2)(B)(iii) and 1934(f)(2)(B)(iii) of the Act, the IDT approach to care management and service delivery is a requirement that cannot be waived. However, the PACE statutes do not specifically address the composition of the IDT.

As we explained in the proposed rule, we continue to believe that a well-

functioning IDT is critical to the success of the PACE program, as the team is instrumental in controlling the delivery, quality, and continuity of care. As we stated in the proposed rule (81 FR 54683) and the 1999 IFC (64 FR 66248), members of the IDT should be knowledgeable about the overall needs of the patient, not just the needs which relate to their individual disciplines. In order to meet all of the health, psychosocial, and functional needs of the participant, team members must view the participant in a holistic manner and focus on a comprehensive care approach. We noted in the proposed rule that we considered whether to provide even greater flexibility to POs, while maintaining our expectation of a well-functioning, knowledgeable IDT, by deleting the IDT composition requirements in § 460.102(b). Under this alternative approach, we 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. Similar to the revisions to § 460.102(c), we would require that primary care be furnished by a PACE primary care provider. CMS and the SAA would continue to monitor POs to ensure that participants are receiving all necessary care. We noted that these monitoring activities would serve as a safeguard to help ensure there is no negative impact to the quality of care being provided. We stated that we believed 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. We solicited public comments on this approach. A discussion of the comments we received on this option, and our response to those comments, appears below.

*Comment:* Most commenters expressed opposition to deleting IDT composition requirements. Several suggested that we retain the composition requirement for an IDT but modify it to allow for a range of health professionals and functions that participate in assessment and care planning based on the needs of individual PACE participants. One commenter thought that we should continue to require every member of the IDT to be present in the development of a participant's plan of care.

*Response:* We thank the commenters for their input on the first proposed alternative approach. In response to a majority of commenters who expressed concern regarding the deletion of IDT composition requirements, we have determined that the current requirements should be retained at this time.

As discussed in the proposed rule, in the second alternative, we considered deleting § 460.102(d)(3), which requires that members of the IDT must serve primarily PACE participants. Again, this requirement was based on the PACE Protocol, which has now been replaced by the PACE program agreement. As we stated in the proposed rule (81 FR 54683), the 1999 IFC (64 FR 66249) and the 2006 final rule (71 FR 71286), for a frail elderly population, such as is served by the PACE program, it is important to support and retain measures that promote quality and continuity of care. We explained that if team members serve primarily PACE participants, they are able to develop a rapport with participants and are better able to plan for and provide their care. Over the years, we have received and approved numerous requests to waive the ''primarily served'' requirement for members of the IDT, such as the primary care physician or the Master's-level social worker, in order to allow POs needed flexibility in staffing their IDTs. We have not encountered any issues or concerns after granting such waivers. Thus, we solicited public comments on whether we should extend this flexibility to all POs without the need to request a waiver.

*Comment:* Most commenters concurred with eliminating the ''primarily served'' requirement for community-based physicians and suggested also eliminating the requirement for other types of community-based providers and all members of the IDT. In addition, some commenters believed that the current requirement, *i.e.* ''primarily serve'' is vague and has led to misinterpretations of this requirement. In addition, commenters emphasized the operational challenges POs face, which can lead to a need for qualified staff that can serve on a part-time, rather than full-time basis. Other commenters stated that the use of community-based physicians has expanded the range of primary care providers PACE participants can choose from, and in many cases has permitted participants to retain their existing primary care physician when enrolling in PACE. A few commenters recommended retaining the ''primarily served'' requirement and expressed concern that members of the IDT should be knowledgeable and experienced with the needs of the PACE population. One commenter acknowledged that including community-based physicians on the IDT likely promotes continuity of care for newly-enrolled participants, but may cause conflicts regarding treatment and the approval of services over time. This commenter asserted that the inclusion of community-based physicians should continue to be addressed through the waiver process. Other commenters supported the proposals but indicated that protections must be in place to ensure the integrity of the PACE organization's mission.

*Response:* We have carefully considered the comments we received on this proposal, as well as the comments we received on the similar proposal related to community-based physicians. Overall, commenters were very supportive of the change to eliminate the ''primarily served'' requirement for individuals who serve on the IDT. However, some commenters expressed concerns about eliminating this requirement based on the belief that providers that primarily serve PACE participants, with presumably more direct and extensive experience rendering care to the PACE population, would be best positioned to understand and address the needs of those participants. While we understand this concern, we believe that community-based providers, regardless of their experience serving a PACE population, nonetheless must have the requisite expertise and ability to practice within the scope of their licensure. As long as these community-based providers are willing to fulfill the requirements for members of the IDT, we do not believe they should be precluded from doing so based on a requirement that they ''primarily serve'' PACE participants. Comments received were supportive of our proposals overall and support our conclusion that the benefits of requiring IDT members to have experience serving PACE participants, in and of itself, do not outweigh the benefits of eliminating the ''primarily served'' requirement. We note, as did certain commenters, that a number of waivers have been granted of the ''primarily served'' requirement for members of the IDT in recent years, with beneficial results. Furthermore, we are not aware of any adverse impact in overall quality of care for POs operating under such waivers. We agree with commenters that use of community-based providers has promoted continuity of care, allowed POs greater flexibility in the delivery of primary care to participants, and has increased operating efficiencies without compromising quality of care. We note that quality of care provided by POs will continue to be a focus of CMS and SAA oversight and monitoring activities. By reducing operational challenges and expanding PACE participant provider

choices, we continue to support efforts to ensure PACE participants have access to quality care and qualified providers. Based on the supportive comments we received, as well as our positive experience in granting waivers of the ''primarily served'' requirement, we are revising the regulations to delete the requirement that members of the IDT must serve primarily PACE participants. Specifically, we will update the regulation by removing § 460.102(d)(3).

4. Participant Assessment (§ 460.104)

Section 460.104 sets forth the requirements for PACE participant assessments. As we explained in the proposed rule (81 FR 54683) and the 2006 final rule (71 FR 71288), the information obtained through the participant assessment is the basis for the plan of care developed by the IDT. As such, it is important that the assessment be as comprehensive as possible to capture all of the information necessary for the IDT to develop a plan of care that will adequately address all of the participant's functional, psychosocial, and health care needs.

Section 460.104(a) sets forth the requirements for the initial comprehensive assessment, which must be completed promptly following enrollment. Currently all members of the IDT must be present for the initial assessment, representing each required clinical discipline to appropriately assess the PACE participant's holistic needs and develop a customized plan of care. We stated in the proposed rule that, under our proposal to modify § 460.102, to the extent an IDT member serves multiple roles on the IDT, that member may represent the clinical expertise for which he or she is qualified. Other team members may be present as necessary. In § 460.104(a)(2), we state that certain members of the IDT must evaluate the participant in person as part of the initial comprehensive assessment but, in paragraph (a)(1), we do not specify that the initial comprehensive assessment must be an in-person assessment. Therefore, we proposed to add the phrase ''in-person'' after ''initial'' in paragraph (a)(1). We explained that our longstanding policy has been that the initial assessment is an in-person assessment, so the addition of this language should make this requirement clear but not change the current practice. We also proposed to change the requirement that the initial comprehensive assessment be completed ''promptly following enrollment'' to ''in a timely manner in order to meet the requirements in paragraph (b) of this section.'' We noted in the proposed rule that this would allow the PO to complete this assessment at a time that works for the PO, but within a timely manner so as to allow the IDT to complete the development of the plan of care within 30 days of the date of enrollment.

Currently, during the initial comprehensive assessment, a primary care physician must evaluate the participant and develop a discipline-specific assessment of the participant's health and social status. We proposed to change ''primary care physician'' to ''primary care provider'' in paragraphs (a)(2)(i) and (c)(1) to be consistent with proposed changes to the composition of the IDT in § 460.102. As discussed in section III.G.2. of this final rule, we proposed that the primary care physician role be changed to primary care provider to allow other licensed primary care providers (specifically, nurse practitioners, physician assistants, and community-based physicians) to be part of the core IDT.

In § 460.104(a)(2), we proposed to remove the reference to IDT members initially evaluating participants ''at appropriate intervals'' because the scheduling of the discipline-specific assessments as part of the initial comprehensive assessment is up to the POs, and we believed stating that they must occur ''at appropriate intervals'' is unnecessary and superfluous language. We proposed to change the language in § 460.104(a)(3) from ''individual team members'' to ''the interdisciplinary team'' so that language is consistent throughout these regulations and because it is the IDT's decision whether to include other professionals in the initial comprehensive assessment. Additionally, we proposed to add the word ''initial'' before ''comprehensive assessment'' so it is clear that professionals may be included in the initial comprehensive assessment, as opposed to a reassessment. We proposed two changes to § 460.104(a)(4) to clarify that the initial comprehensive assessment covers all aspects of the participant's physical, social, and mental needs. Currently, the heading is titled ''Comprehensive assessment criteria.'' We proposed to revise the heading to ''Initial comprehensive assessment criteria.'' We also proposed to add ''in-person'' to this section to make it consistent with the terminology in § 460.104(a)(1) and (2). We stated in the proposed rule that we believed an initial comprehensive assessment is a more valuable tool for identifying the participant's need for services when performed in person.

Section 460.104(b) states that the IDT must ''promptly'' consolidate discipline-specific assessments into a single plan of care for each participant through discussion ''in team meetings.'' We noted in the proposed rule that the term ''promptly'' does not provide definitive direction for an IDT to know when the discipline-specific assessment should be completed and incorporated into a plan of care. We proposed to change this provision to specify that the plan of care must be completed ''within 30 days of the date of enrollment'' to remove the ambiguity of ''promptly.'' We stated that we believed 30 days balances the need for time to complete these activities with the need to complete these activities within a reasonable amount of time.

Moreover, we noted in the proposed rule, it is our understanding that some POs interpret the term ''team meeting'' as requiring members of the IDT to be physically present in the meeting. We stated that we believed POs need the 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. In paragraph (b), we proposed to change the words ''discussion in team meetings'' to ''team discussions'' to indicate that there must be a team discussion, but the format (for example, video conferencing, conference call, or in-person meeting) and location of the discussion would be at the discretion of the PO.

We also proposed to create a new paragraph under § 460.104(b). Under new paragraph (b)(1), we proposed to state that if the IDT determines from its assessment that any services associated with the comprehensive assessment criteria listed in paragraph (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. We explained in the proposed rule that if the IDT does not believe a PACE participant needs a certain service as it relates to the IDT care plan assessment findings, and therefore, does not authorize that service, the IDT must document the rationale for not including the service in the plan of care. We noted that we would expect the plan of care to reflect that the participant was assessed for all services even where a determination is made that certain services were unnecessary at that time. We proposed to move the current requirement in paragraph (b)—that female participants must be informed that they are entitled to choose a qualified specialist for women's health services from the PO's network to furnish routine or preventive

women's health services—to new paragraph (b)(2).

Currently, § 460.104(c) sets forth the requirements for periodic reassessments, including semiannual and annual reassessments. Section 460.104(d) discusses the requirements for unscheduled reassessments. We noted in the proposed rule that our experience has demonstrated that the requirement to perform both semiannual and annual reassessments can be overly burdensome and unnecessary in that participants are consistently being monitored for changes and are already reassessed whenever there is a change in their health status. Accordingly, we proposed to delete the requirement in paragraph (c)(2) requiring the annual reassessments by the physical therapist, occupational therapist, dietician, and home care coordinator. We proposed to delete corresponding references to annual reassessments in paragraph (d). We proposed to keep the requirement that PACE participants be reassessed semiannually, every 6 months. We stated that we would change the list of IDT members that must conduct the semiannual assessment to include the primary care provider, registered nurse, Master's-level social worker, and any other IDT members actively involved in the development or implementation of the participant's plan of care, as determined by the IDT members whose attendance is required. We noted in the proposed rule that we believed PACE participants should be reassessed at least every 6 months as this will better ensure that PACE participants, who are generally frail, are receiving appropriate treatment. We proposed to remove ''recreational therapist or activity coordinator'' from the list of IDT members that must participate in the semiannual reassessment. As stated in the proposed rule, we believed reducing the number of IDT members who are required to participate in the semi-annual assessment will reduce the burden on POs and allow the POs to allocate their resources more efficiently, while still meeting the care needs of participants. We explained in the proposed rule that POs have reported that recreational therapists and activity coordinators are not needed at every reassessment. POs further report that to require that recreational therapists or activity coordinators be present at every semiannual reassessment is unnecessary and can be overly burdensome. However, recreational therapists and activity coordinators are part of the IDT and can update the IDT on the participants' successes or needs for recreational therapy or involvement in activities. We stated in the proposed rule that we believed the primary care provider, registered nurse, and Master's-level social worker can collectively determine, based on the participant's plan of care and IDT discussions, which other IDT members should be present during the semiannual assessment. As such, we stated that we did not believe we needed to require that the recreational therapist or activity coordinator be present at the semiannual reassessment unless the primary care provider, registered nurse, and Master's-level social worker determine that the recreational therapist or activity coordinator needs to be present because that individual is actively involved in the development or implementation of the participant's plan of care.

The requirements for semiannual reassessments are currently at (c)(1)(i) through (v) and would be redesignated as paragraphs (c)(1) through (c)(4). In the redesignated paragraph (c)(1), we proposed to revise ''physician'' to ''provider'' for consistency. We also proposed to redesignate paragraph (c)(1)(v) as (c)(4) and revise the provision to delete the examples.

Section 460.104(d) discusses unscheduled reassessments. We proposed changes to paragraph (d) to remove the reference to annual reassessments. We proposed to change the language in (d)(1) from ''listed in paragraph (a)(2) of this section'' to ''listed in paragraph (c) of this section.'' As we explained in the proposed rule, this would change the requirement for unscheduled reassessments in the case of a change in participant status so that only the IDT members listed in paragraph (c) will have to conduct the unscheduled reassessment. Specifically, the primary care provider, registered nurse, Master's-level social worker, and other team members actively involved in the development or implementation of the participant's plan of care would conduct the participant's unscheduled reassessment. Similarly, we proposed to change paragraph (d)(2), regarding unscheduled reassessments at the request of the participant or the participant's designated representative, to also align with IDT members listed in paragraph (c). We noted in the proposed rule that we believed reducing the number of IDT members that are required to conduct the unscheduled reassessments would reduce the burden on POs and allow the POs to allocate their resources more efficiently, while still meeting the care needs of participants.

We noted in the proposed rule that, under § 460.64, PO staff with direct participant contact must only act within the scope of their authority to practice. Therefore, if the IDT members believe a participant may need care that is not within the scope of their respective practices, those members would need to involve other IDT members as appropriate. We stated in the proposed rule that, for these reasons, we did not believe we needed to require all core members of the IDT to conduct unscheduled reassessments.

A discussion of the public comments we received on our proposals regarding participant assessments under § 460.104, and our responses to those comments, appears below.

*Comment:* Some commenters did not support the proposed changes to § 460.104(d)(1) and (2) as they believed that not all service requests require an in-person assessment by each of the IDT members included in paragraph (c). These commenters suggested the IDT should retain the ability to determine which members of the IDT should conduct the reassessment, and include those IDT members that are actively involved in the participant's plan of care. Another commenter stated that some PACE participants have become overwhelmed by the large number of IDT members managing their care and, as a result, have disenrolled from the PACE program. Several commenters expressed the need to make the most effective use of IDT resources while meeting the needs of PACE participants. Lastly, a commenter requested that CMS clarify whether it has any concerns that providing POs with this greater flexibility could impact the quality of care for PACE participants.

*Response:* In an effort to align § 460.104(d)(1) and (d)(2), we inadvertently increased the number of IDT members required for in-person reassessments in (d)(2). In support of our efforts to reduce provider burden and balance the needs of PACE participants and PO resources, we believe that POs should retain the ability to identify the appropriate IDT members needed for an unscheduled reassessment at the request of the participant or designated representative as § 460.104(d)(2) currently permits, and we did not intend to require all IDT members referenced in § 460.104(c) to participate in conducting these reassessments. We do not anticipate that maintaining the current requirement will impact the quality of care for PACE participants as we will continue to rely on POs to apply their clinical expertise when conducting unscheduled reassessments and expect that the IDT will involve other IDT members as appropriate.

Based on the comments received about unnecessary and potentially overwhelming IDT member presence at reassessments, as well as the implications of our inadvertent change to align requirements, we are not finalizing the IDT member changes to § 460.104(d)(2) as proposed and will maintain the current requirement.

*Comment:* In general, commenters concurred with the proposed revisions to § 460.104. However, commenters expressed concern regarding the proposed revision to § 460.104(c)(2) that would eliminate the requirement for annual reassessments that include the other team disciplines such as physical therapist (PT), occupational therapist (OT), dietician, and home health coordinator. Commenters stated that by deleting the annual reassessment by the other team disciplines, POs may miss an opportunity to identify new or emergent participant issues. Commenters believed that an annual assessment by these disciplines is beneficial for the PACE participant.

*Response:* We appreciate the comments regarding the role of the other team disciplines, such as PTs, OTs, dieticians and home health coordinators, in patient assessments and that they continue to be included in an annual assessment. However, we will continue to require reassessments to be performed on a semiannual basis, that is, every 6 months. We believe that the primary care provider, registered nurse, and Master's-level social worker who participate in the semiannual reassessment can collectively determine, based on the participant's plan of care and IDT discussions, which other IDT members should be present during this reassessment. We expect the other disciplines, such as OTs and PTs, to be included as needed. As previously stated, PO staff with direct participant contact must only act within the scope of their authority to practice, so if the IDT members listed in paragraph (c) believe a participant may need care that is not within the scope of their respective practices, those members should involve other IDT members as appropriate. For these reasons, after considering the comments, we are finalizing the changes to § 460.104(c)(2) as proposed.

*Comment:* Commenters suggested that we allow POs to conduct in-person initial comprehensive assessments and reassessments using modern technology such as video conferencing, where participants and the IDT members are able to interact ''face-to-face'' and in real time but from different locations. Another commenter requested CMS allow for the use of remote technologies, noting that doing so would be particularly helpful in rural areas due to longer travel times and higher costs associated with conducting in-person reassessments. Other commenters expressed that not all service requests warrant an in-person reassessment. These commenters noted that in some cases, such requests could easily be addressed by the IDT members most familiar with the participant and actively involved in the plan of care. These IDT members would evaluate the request and update the care plan accordingly.

*Response:* We appreciate the recommendations regarding the use of modern technology in conducting initial assessments and reassessments and minimizing the burden associated with in-person reassessments for service requests, especially those requests that do not involve complex clinical decision making and/or input from specialty providers. In addition, we recognize that the current in-person requirements for unscheduled reassessments in response to service requests can sometimes delay access to services because of the time necessary to coordinate among the appropriate IDT members and conduct the in-person reassessment. Based on the comments we received in response to the discussion of PACE participant assessments in the proposed rule, we have carefully examined the reassessment requirements to determine whether it may be appropriate for a reassessment to be conducted via remote technology in some circumstances, as suggested by commenters, to ensure timely delivery of services and reduce burden on POs. As a result of feedback from the industry recommending that we allow the use of remote technology to reduce the burden associated with in-person reassessments, and to more efficiently address the care needs of PACE participants and afford POs more flexibility, we are revising § 460.104(d)(2) to specify that POs may use remote technologies to perform unscheduled reassessments in some circumstances. Specifically, when a participant (or his or her designated representative) makes a request to initiate, eliminate or continue a particular service, also known as a service request, the appropriate members of the IDT, as determined by the IDT, may use remote technologies to conduct unscheduled reassessments when the IDT determines that the use of remote technology is appropriate, the service request will likely be deemed necessary to improve or maintain the participant's overall health status, and the participant or his or her designated representative agrees to the use of remote technology. While we are not eliminating the requirement to perform unscheduled reassessments in response to service requests, or to conduct those reassessments in person in certain cases, we believe that permitting POs to use remote technologies to conduct reassessments under the circumstances described above will facilitate appropriate evaluation of PACE participants and promote the timely delivery of care and effective communication between the IDT and the participant and his or her designated representative. The regulation will continue to require POs to conduct a reassessment in response to a service request. However, we are revising the regulation to allow the appropriate member(s) of the IDT, as identified by the IDT, to conduct the reassessment using remote technology in specific circumstances. We expect that POs will use remote technology for service requests that are necessary to maintain participants' health and well-being in the community setting, and may include services such as improving sanitary conditions in the home, respite care, or items needed to manage and treat non-complex medical conditions. Additionally, POs must still conduct an in-person reassessment prior to denying a service delivery request and cannot use remote technology to conduct these reassessments.

We want to emphasize that remote technologies should be used on a case-by-case basis and may not be appropriate for participants that have complex medical needs and/or require a more hands-on approach for conducting unscheduled reassessments. We expect IDT members to utilize their clinical judgment in determining when remote technologies are appropriate and when an unscheduled reassessment should be conducted in-person, without using remote technologies.

In addition, we expect that circumstances may arise that warrant a follow-up ''in-person'' reassessment. For example, during an unscheduled reassessment initially conducted using remote video technology, the IDT may determine that a more extensive evaluation is needed that cannot be accomplished through remote technologies. We consider remote technologies that allow interactive and immediate dialogue between the IDT and the PACE participant, caregiver, and/or designated representative to be appropriate for conducting reassessments. This includes reassessments via telephone, video

conferencing, live instant messaging and chat software, or other media that allow sufficiently direct and interactive communication to permit the IDT to assess the participant's health status and evaluate the need for a particular service.

Based on our audit findings and general oversight of POs, we have found that the majority of service requests are approved, and can and should be processed by POs in a more expeditious manner. Audits conducted during calendar years 2017 and 2018 found that many service requests were not processed in a timely manner, leading to delays in the provision of the requested service. According to the 2017 PACE Annual Report, 55 out of 74 POs were cited for not processing service requests in a timely manner. Feedback from the POs suggests that the administrative burden associated with conducting in-person reassessments often causes delays in processing service requests and decision making regarding whether to approve or deny a request. Because the majority of service requests are approved, we have determined that the use of remote technologies is most appropriate for this type of unscheduled reassessment because it will reduce travel times and help to more expeditiously connect the IDT to PACE participants in the community, especially those who reside in rural settings and/or receive the majority of care in settings outside the PACE center due to physical or cognitive limitations or participant preference. We also believe this policy will help to prevent delays in care for fairly straightforward service requests that do not involve complex clinical decision making.

We emphasize that the use of remote technologies will be voluntary for participants, and POs cannot mandate that participants and/or their caregivers or designated representatives utilize such technologies during unscheduled reassessments. If a participant does not wish to allow for reassessments to be conducted with remote technologies, the IDT must conduct the reassessment in-person without using remote technology.

We encourage POs to utilize remote technologies as appropriate to improve communication with participants in all aspects of care delivery, however, use of remote technology does not supersede requirements that mandate in-person reassessments. This includes unscheduled reassessments at the request of the participant or designated representative where the PO would deny a request; under § 460.104(d)(2), we will continue to require POs to conduct an in-person reassessment before denying a request from a PACE participant.

The timeframe for notifying the participant or designated representative of the PO's decision to approve or deny the request will remain unchanged, and must be done in accordance with § 460.104(d)(2)(ii) through (iv). We also note that under § 460.104(e)(4), POs must furnish any approved services in the revised plan of care as expeditiously as the participant's health condition requires.

Lastly, at this time we do not believe it would be appropriate to conduct initial comprehensive assessments and other periodic reassessments through remote technologies. These assessments must continue to be performed in-person without the use of remote technology because they help to establish and/or maintain the therapeutic relationship between PACE participants and/or their caregivers and the PO, and we do not want to create circumstances in which the IDT misses an opportunity to identify new or emergent participant issues due to the inherent limitations of remote technologies, especially in circumstances where a more hands-on approach and/or in-person visualization is needed to more accurately and effectively evaluate participant care needs. In summary, with the exception of IDT member requirements in § 460.104(d)(2), we are finalizing all the other changes to § 460.104 as proposed. In addition, based on public comments, we are further amending the regulation in § 460.104(d)(2) to allow for the use of remote technologies to conduct unscheduled reassessments in response to service delivery requests when the IDT determines that the use of remote technology is appropriate and the service request will likely be deemed necessary to improve or maintain the participant's overall health status and the participant or his or her designated representative agrees to the use of remote technology.

5. Plan of Care (§ 460.106)

Section 460.106 requires that the IDT establish, implement, coordinate, and monitor a comprehensive plan of care for each participant. As we noted in the proposed rule, the purpose of the plan of care is to help support the identification of potential or actual areas of improvement and monitor progression and outcomes. The current regulatory language pertaining to the basic requirement and the content of the plan of care in this section has been described by POs as confusing and unclear. Therefore, we proposed to revise this section by adding requirements to provide more clarity without changing the fundamental aspects of the plan of care process.

First, we proposed to change § 460.106(a) from requiring that a plan of care be developed promptly to state that the plan of care must be developed ''within 30 days of the date of enrollment.'' We explained in the proposed rule that the term ''promptly'' does not provide definitive direction for an IDT to know when the discipline-specific assessments under § 460.104(b) should be completed and incorporated into a plan of care. Requiring that the plan of care be developed within 30 days of the date of enrollment balances the need for time to complete the assessments and develop a plan of care with the need to complete the plan of care within a reasonable timeframe. We noted that this proposed change is consistent with the proposed changes to § 460.104(b).

Next, we proposed to add language to clarify which members of the IDT are required to develop the plan of care within 30 days. The proposed language stated that the IDT members specified in § 460.104(a)(2) must develop the plan of care for each participant based on the initial comprehensive assessment findings. We noted in the proposed rule that the added language aimed to clarify for POs which members of the IDT should develop the plan of care. The IDT members in § 460.104(a)(2) are members of the IDT that are required to conduct the initial comprehensive assessment and would remain responsible for developing the plan of care based on the initial discipline-specific assessments. We acknowledge here that both §§ 460.104(b) and 460.106(a) mention the development of a plan of care, however, only § 460.106(a) includes changes that reference the IDT members in § 460.104(a)(2). We clarify here that the intent of § 460.104(b) is to achieve consensus among all IDT team members in developing one single plan of care, and that requirement is unchanged in this rule. The changes to § 460.106(a) specify which IDT members must be involved in the development of the plan of care based on their expertise and insights gained from conducting those comprehensive initial assessments, while § 460.104(b) maintains the requirement that the single plan of care must have the consensus of all IDT members through team discussions with the full IDT as indicated in the regulation and preamble discussions. In other words, while the eight disciplines responsible for conducting initial assessments will actively develop the proposed plan of care, the care plan

cannot be finalized without a team discussion with the full IDT included in § 460.102(b)(1) through (11) to gather input from all remaining IDT members and consensus from the full team. We believe that all members of the IDT bring valuable perspectives to this process and therefore reiterate that the changes to the IDT members required to develop the plan of care in § 460.106(a) do not impact the requirement in § 460.104(b) that all IDT members agree upon the plan of care through team discussions.

Section 460.106(b) sets forth the content of the plan of care and states that the plan of care must meet the following requirements:

- Specify the care needed to meet the participant's medical, physical, emotional and social needs, as identified in the initial comprehensive assessment;
- Identify measurable outcomes to be achieved.

We noted in the proposed rule that we believed these requirements are appropriate, but may have, in the past, led to confusion regarding the overall purpose, goal, creation, implementation and follow-up process of the plan of care. We stated that current regulations do not explicitly require POs to follow industry standards in developing and following care plan interventions. We noted that we believed adding new requirements will help POs to effectively and efficiently identify and address each participant's care planning needs. Therefore, we proposed to add three new requirements to § 460.106(b). In paragraph (b)(3), we proposed to require that the plan of care utilize the most appropriate interventions (for example, care improvement strategies) for each of the participant's care needs that advances the participant toward a measurable goal and desired outcome. In paragraph (b)(4), we proposed to require that the plan of care identify each intervention and how it will be implemented. We stated in the proposed rule that interventions should be targeted, specific actions implemented to improve a participant's health care outcome. And finally, in paragraph (b)(5), we proposed to require that the plan of care identify how each intervention will be evaluated to determine progress in reaching specified goals and desired outcomes.

The following is a summary of the public comments we received on the proposed changes to the plan of care requirements in § 460.106 and our responses to comments.

*Comment:* Overall, commenters supported the proposed revisions to § 460.106. A few commenters urged CMS to provide exceptions for extenuating circumstances (such as when a participant is hospitalized or out of the service area during the initial 30 days of enrollment, or services are disrupted due to catastrophic weather-related events) to the requirement for developing a comprehensive plan of care within 30 days of the date of enrollment.

*Response:* In consideration of the supportive comments, we are finalizing this provision as proposed. However, we wish to address the recommendation regarding an exception to the requirement for developing a comprehensive plan of care within 30 days of the date of enrollment due to extenuating circumstances. We recognize that there may be circumstances, albeit rare, that would prevent a PO from conducting a timely comprehensive assessment for newly-enrolled PACE participants. However, this is a fundamental part of care planning and is key to a PO's ability to fulfill its mission and provide quality care to its participants. Therefore, it is our expectation that POs will comply with the 30-day timeframe in § 460.106(b) and make every effort to conduct timely assessments in order to develop and begin to implement the individualized plan of care in a timely manner. In those rare situations in which the circumstances prevent a timely assessment, and development of a plan of care, the PO is expected 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.

*H. Subpart G—Participant Rights*

1. Specific Rights to Which a Participant Is Entitled (§ 460.112)

Section 460.112 describes the specific rights of PACE participants, including, in paragraph (b)(1), the right to be fully informed in writing of services available from the PO:

- Before enrollment;
- At enrollment; and
- At the time a participant's needs necessitate the disclosure and delivery of such information to allow informed choice.

We proposed to combine paragraphs (b)(1)(i) and (b)(1)(ii) into proposed paragraph (b)(1)(i) to state that information about PACE services will be provided ''prior to and upon enrollment'' in the PO, and to redesignate current paragraph (b)(1)(iii) as paragraph (b)(1)(ii), in an effort to simplify the language and regulatory construction.

Section 460.112(b)(3) states that each participant has the right to examine, or upon reasonable request, to be assisted in examining the results of the most recent review of the PO conducted by CMS or the SAA and any plan of correction in effect. We proposed to make a technical change to § 460.112(b)(3) by deleting the language ''to be assisted'' and replacing it with ''to be helped.'' The changes to § 460.112(b) are not substantive in nature but are intended to simplify the regulatory language.

Sections 1894(c)(5)(A) and 1934(c)(5)(A) of the Act provide that participants must be permitted to voluntarily disenroll from PACE without cause at any time. Accordingly, § 460.112(c)(3) states that each PACE participant has the right to disenroll from the program at any time. We explained in the proposed rule that we have operationalized this requirement by allowing participants to provide notice of voluntary disenrollment at any time and making that disenrollment effective on the first day of the month after the PO receives the notice. Consistent with our current practice, we proposed to revise paragraph (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 PO receives the participant's notice of voluntary disenrollment as set forth in § 460.162(a). As discussed in the proposed rule (81 FR 54686) and section III.J.5. of this final rule, we proposed a corresponding revision to § 460.162 that would state, in a new paragraph (a), that a voluntary disenrollment is effective on the first day of the month following the date the PO receives the participant's notice of voluntary disenrollment. We explained in the proposed rule that, because POs receive a monthly capitation payment from Medicare and/or Medicaid in advance, we effectuate the disenrollment at the end of the capitated payment period.

We received no comments on our proposed revisions to § 460.112, and therefore, we are finalizing this provision as proposed.

2. Explanation of Rights (§ 460.116)

Section 460.116 sets forth requirements for POs with respect to explanation of rights, such as having written policies and procedures on these rights, explaining the rights, and displaying the rights. Section 460.116(c)(1) provides that the PO must write the participant rights in English and in any other principal languages of the community. Consistent with the

proposal regarding marketing materials under § 460.82(c)(1), discussed in section III.F. of this final rule, we proposed to specify that if a state has not established a standard for making the principal language determination, a principal language of the community is any language spoken in the home by at least 5 percent of the individuals in the PO's service area. As we explained in the proposed rule, we established a similar 5 percent language threshold for marketing materials in the MA program (§ 422.2264(e)), and we believed this threshold is also appropriate for PACE because of the similarities in population make-up between the MA program and PACE. Moreover, we noted in the proposed rule, we strive to create harmony across program requirements when feasible. This reduces complexity for those organizations that operate multiple programs.

Section 460.116(c)(2) states that the PO must display the participant rights in a prominent place in the PACE center. We proposed to add the word ''PACE'' before the words ''participant rights'' to specify that participant rights specific to PACE must be displayed. We explained in the proposed rule that during CMS audits of POs, we have observed that POs have displayed rights pertaining to the adult day center or other rights, and not those specific to the PACE program, in the PACE center. As proposed, the language would explicitly state that the PACE participant rights must be posted in the PACE center. We received no comments on our proposed changes to § 460.116, and therefore, we are finalizing the changes as proposed.

3. PACE Organization's Appeals Process (§ 460.122)

Section 460.122 sets forth the requirements for a PO's appeals process. Section 460.122(c)(1) states that a PO's appeals process must include written procedures for timely preparation and processing of a written denial of coverage or payment as provided in § 460.104(c)(3). In the 2006 final rule, we redesignated paragraph (c)(3) to paragraph (d) in § 460.104, but we inadvertently did not make the corresponding change to the citation referenced in § 460.122(c)(1) (71 FR 71292, 71336, and 71337). Therefore, we proposed to amend § 460.122(c)(1) to provide the correct citation reference to the standards for a written denial notice by changing it from § 460.104(c)(3) to § 460.104(d)(2)(iv).

We did not receive any comments on our proposed technical change to § 460.122(c)(1). Therefore, we are finalizing this provision as proposed.

*I. Subpart H—Quality Assessment and Performance Improvement*

As discussed in section III.A. of this final rule, to update the terminology to comport with that used in other CMS programs, we proposed to replace all references to ''quality assessment'' and ''performance improvement'' with ''quality improvement'' throughout part 460, including the heading for subpart H and the titles of various sections. In this section, we discuss the other changes that we proposed to subpart H.

1. General Rule (§ 460.130)

Sections 1894(e)(3)(B) and 1934(e)(3)(B) of the Act require that, under a PACE program agreement, the PO, CMS, and the SAA shall jointly cooperate in the development and implementation of health status and quality of life outcome measures with respect to PACE participants. Section 460.130 requires a PO to develop, implement, maintain, and evaluate a quality assessment and performance improvement program, which reflects the full range of services furnished by the PO. Further, a PO must take actions that result in improvement in its performance in all types of care.

Section 460.140 refers to additional quality assessment activities related to reporting requirements. We proposed to move the requirement in § 460.140 to § 460.130 as new paragraph (d), so that all of the general rules for quality improvement would be part of the first section in subpart H. As we noted in the proposed rule, this change would leave no requirements under § 460.140, so we also proposed to remove § 460.140.

2. Quality Assessment and Performance Improvement Plan (§ 460.132)

Section 460.132 sets forth our current requirements with respect to a Quality Assessment and Performance Improvement (QAPI) plan. We proposed to revise the requirements for a QAPI plan in § 460.132. In addition to the terminology change that we discussed previously (replacing all references to ''quality assessment and performance improvement'' with the term ''quality improvement''), we proposed to revise paragraph (a) to require a PO to have a written quality improvement plan that is collaborative and interdisciplinary in nature. As we explained in the proposed rule, the PACE program is unique in its structure in that it has a collaborative and interdisciplinary approach in treatment of PACE participants. We stated that we believed a PO's quality improvement plan should reflect this collaboration and interdisciplinary approach in its improvement goals. That is, any 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. For example, 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 (for example, 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. We explained in the proposed rule that we believed requiring a collaborative and interdisciplinary quality improvement plan will help POs identify and improve PACE quality issues more appropriately. Therefore, we proposed to revise paragraph (a) to require a PO to have a written quality improvement plan that is collaborative and interdisciplinary in nature.

3. Additional Quality Assessment Activities (§ 460.140)

As discussed in section III.I.1. of this final rule, we proposed to redesignate the content of § 460.140 to § 460.130, and therefore, we proposed to remove § 460.140.

The following is a summary of the public comments we received on the proposed changes to the quality requirements in subpart H and our responses to comments.

*Comment:* We only received comments on the proposed revision to § 460.132. The many comments we received were all in favor of the proposed revision. Commenters believed that the term ''collaborative and interdisciplinary in nature'' accurately describes the quality improvement plans that POs have under the current requirements. One commenter recommended that CMS also require POs to solicit ongoing collective input from individuals and their families and caregivers when developing quality improvement plans. Another commenter urged CMS to put additional protections in place to ensure that any quality improvement plan is comprehensive and accounts for care provided across the ''care'' continuum and in various settings.

*Response:* We appreciate the comments and are finalizing the

modifications to § 460.132 and the other changes to subpart H as proposed. Regarding the two recommendations we received on quality improvement plans, we will take this input into account as we consider future subregulatory guidance or rulemaking on PACE quality requirements.

*J. Subpart I—Participant Enrollment and Disenrollment*

1. Eligibility to Enroll in a PACE Program (§ 460.150)

In accordance with sections 1894(a)(5) and (c)(1) and 1934(a)(5) and (c)(1) of the Act, we established § 460.150 to specify the requirements for eligibility to enroll in a PACE program.

Section 460.150(c)(1) provides that, at the time of enrollment, an individual must be able to live in a community setting without jeopardizing his or her health or safety, and § 460.150(c)(2) states 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 specified in the program agreement. As we explained in the proposed rule (81 FR 54687) and the 2006 final rule (71 FR 71309), determining whether an individual's health or safety would be jeopardized by living in the community involves assessing the individual's care support network, as well as the individual's health condition. This assessment is done by the PO based upon criteria established by the state and specified in the PACE program agreement. We proposed to codify this longstanding policy in our regulations by revising § 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.

A discussion of the public comments we received on this proposal, and our responses to those comments, appears below.

*Comment:* Several commenters expressed support for our proposal to codify the longstanding policy of using criteria developed by the SAA to determine if an individual's health or safety would be jeopardized by living in a community setting. Another commenter recommended that we develop a new PACE eligibility criterion for individuals who are institutionalized but have a realistic potential to return to their homes. Another commenter requested that CMS work with states to ensure that SAA criteria are sufficiently clear, so as to ensure consistent application.

*Response:* We thank the commenters for their support. We did not propose any additional criteria for PACE eligibility, and therefore, we believe the comment regarding development of a new PACE eligibility criterion is outside of the scope of this regulation. With regard to the request for us to work with states to ensure that the SAA criteria they develop are clear, we believe that since the states are responsible for developing the criteria, it is also the states' responsibility to ensure the criteria are sufficiently clear.

*Comment:* One commenter requested that in developing the final rule we take into consideration the systems and protocols implemented by states to process PACE eligibility determinations and that we allow for flexibility in our requirements and accommodate the various state protocols, some of which may provide beneficiary protections in addition to what CMS requires.

*Response:* We did not propose any changes to the requirements for determining eligibility for PACE, and therefore, we believe this comment is outside of the scope of this regulation. We are finalizing this provision as proposed.

2. Enrollment Process (§ 460.152)

Section 460.152 specifies the PO's responsibilities during the intake process and actions required in the event a potential PACE participant is denied enrollment because his or her health or safety would be jeopardized by living in a community setting. Section 460.152(b)(4) states that the PO must notify CMS and the SAA if a prospective participant is denied enrollment because his or her health or safety would be jeopardized by living in a community setting and make the documentation available for review. We proposed to add language to paragraph (b)(4) to require that such notification be in the form and manner specified by CMS, as this would reflect our current practice of requiring POs to provide these notifications to CMS and the SAA electronically.

We received no comments on our proposal to require that notification to CMS and the SAA be in the form and manner specified by us; therefore, we are finalizing this provision as proposed.

3. Enrollment Agreement (§ 460.154)

Section 460.154 specifies the general content requirements for the enrollment agreement. Section 460.154(i) states that the enrollment agreement must contain a notification that enrollment in PACE results in disenrollment from any other Medicare or Medicaid prepayment plan or optional benefit. It further provides that electing enrollment in any other Medicare or Medicaid prepayment plan or optional benefit after enrolling as a PACE participant is considered a voluntary disenrollment from PACE. We explained in the proposed rule that we were concerned about possible misinterpretations of this provision, and therefore, we proposed to add language to paragraph (i) to state that if a Medicaid-only or private pay PACE participant becomes eligible for Medicare after enrollment in PACE, he or she will be disenrolled from PACE if he or she elects to obtain Medicare coverage other than from his or her PO.

A discussion of the public comment we received on this proposal, and our response to this comment, appears below.

*Comment:* One commenter expressed support for our proposal and urged us to ensure that messaging regarding the potential for disenrollment be clear and easy to understand in PACE participant materials.

*Response:* We thank the commenter for its support. We will take the suggestion regarding clear messaging into consideration when developing additional subregulatory guidance on PACE disenrollment and beneficiary protections. We are finalizing this provision as proposed.

4. Other Enrollment Procedures (§ 460.156)

Section 460.156 specifies the documentation and information that a PO must provide to a PACE participant who signs an enrollment agreement, as well as to CMS and the SAA. Sections § 460.156(a)(2) and § 460.156(a)(4) state that, after the participant signs an enrollment agreement, the PO must give the participant a PACE membership card and stickers for his or her Medicare and Medicaid cards, as applicable, which indicate that he or she is a PACE participant and include the phone number of the PO, respectively. We proposed to delete the sticker requirement currently at § 460.156(a)(4) and revise the PACE membership card requirement at § 460.156(a)(2) so the PO would give the participant a PACE membership card that indicates that he or she is a PACE participant and that includes the phone number of the PO. As we noted in the proposed rule, this would not only ensure that the participant's Medicare and Medicaid cards are not damaged if stickers are removed in the event the participant disenrolls from PACE, but also would save participants from having to carry their Medicare and Medicaid cards with them, a practice we generally discourage

based on the risk that a beneficiary's personal information may be lost or exposed.

A discussion of the public comments we received on this proposal, and our responses to those comments, appears below.

*Comment:* Commenters were generally supportive of our proposal to delete the sticker requirement and revise the PACE membership card requirement. One commenter stated that this change may result in POs having to reissue all PACE membership cards, which could impose additional administrative burdens on the POs.

*Response:* We appreciate the commenters' support for this change. With regard to the potential for additional administrative burden, we note that this change relieves POs of the requirement to produce and distribute additional materials (that is, the stickers) for participants' Medicare and Medicaid cards. Moreover, POs are already required to provide PACE membership cards. While the new requirement to include the PO's phone number on the PACE membership card will affect some POs that do not currently include contact information on their cards, we believe most POs include this information already. Further, the elimination of the sticker requirement will lessen ongoing burden and costs for POs. Therefore, we are finalizing this provision without modification.

*Comment:* One commenter requested that CMS revise the enrollment effective date requirement in § 460.158 to enable enrollment to become effective on the date of the signed enrollment agreement. The commenter stated that the current enrollment period (effective the first day of the calendar month following the date of the executed enrollment agreement) causes delays in obtaining PACE services and PACE participant and family dissatisfaction.

*Response:* Consistent with the PACE Protocol (64 FR 66300), we established in § 460.158 that a participant's enrollment in the program is effective the first day of the calendar month following the date the PO receives the signed enrollment agreement. We did not propose any changes to § 460.158 in the proposed rule, and therefore, we believe this comment about revising the enrollment agreement effective date is outside the scope of this rule. In addition, we note that enrollment of individuals and payment to POs is based on whole calendar months. In other words, Medicare and Medicaid capitation payments are paid to a PO for an entire month and are not pro-rated. Medicare and Medicaid capitation payment in whole month increments is consistent with the requirement that enrollment in a PO is always effective on the first calendar day of a month and disenrollment is always effective on the last calendar day of a month. Given that both enrollment and Medicare and Medicaid payment occur in whole month increments, we would be unable to accommodate such a request for a change to § 460.158.

5. Voluntary Disenrollment (§ 460.162)

In accordance with sections 1894(c)(5)(A) and 1934(c)(5)(A) of the Act, § 460.162 states that a PACE participant may voluntarily disenroll without cause from the program at any time. We proposed to retain this language in new paragraph (b) and add new paragraphs (a) and (c). As described previously in our discussion of proposed changes to § 460.112(c)(3), we have operationalized the statutory requirements regarding voluntary disenrollment by allowing participants to provide notice of voluntary disenrollment at any time and making that disenrollment effective on the first day of the month after the PO receives the notice. To align with the proposed changes in § 460.112(c)(3) and our current practices for Medicare health plan disenrollment, in paragraph (a), we proposed to add language stating that a participant's voluntary disenrollment is effective on the first day of the month following the date the PO receives the participant's notice of voluntary disenrollment.

Sections 1894(c)(5)(A) and 1934(c)(5)(A) of the Act state that enrollment and disenrollment of PACE program eligible individuals in a PACE program must be under regulations and the PACE program agreement with certain statutory restrictions. Moreover, sections 1894(b)(1)(A)(i) and 1934(b)(1)(A)(i) of the Act state that, under the PACE program agreement, a PO must provide all items and services covered under titles XVIII (Medicare) and XIX (Medicaid). As we stated in the proposed rule, through record review during on-site audits and follow-up regarding family or participant grievances and complaints, we have encountered some instances in which a participant needed additional services and was encouraged to voluntarily disenroll by either an employee or a contractor of the PO in an effort to reduce costs for the PO. To help prevent this practice, we proposed to affirmatively require at § 460.162(c) 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. We noted in the proposed rule that, under § 460.40(c), a PO would be subject to sanctions for engaging in this type of behavior—that is, discriminating in disenrollment among Medicare or Medicaid beneficiaries on the basis of an individual's health status or need for health care services.

A discussion of the public comments we received on our voluntary disenrollment proposals, and our responses to those comments, appears below.

*Comment:* One commenter requested that we create an exception to the voluntary disenrollment effective date for participants electing the Medicare hospice benefit and allow voluntary disenrollments for those individuals to be effective prior to the first day of the month following the date the PO receives the participant's notice of voluntary disenrollment. The commenter stated that the current requirement may delay the start of hospice services and can lead to dissatisfaction for participants and their family members.

*Response:* Enrollment of individuals and payment to POs is based on whole calendar months. In other words, Medicare and Medicaid capitation payments are paid to a PO for an entire month and are not pro-rated. Medicare and Medicaid capitation payment in whole month increments is consistent with the requirement that enrollment in a PO is always effective on the first calendar day of a month and disenrollment is always effective on the last calendar day of a month. Given that both enrollment and Medicare and Medicaid payment occur in whole month increments, we are unable to accommodate the request for an exception for participants electing the Medicare hospice benefit. Therefore, we are finalizing the proposed change to § 460.162(a) without such an exception.

*Comment:* Several commenters opposed the proposal to revise § 460.162 to specify that a participant's voluntary disenrollment is effective on the first day of the month following the date the PO receives the participant's notice of voluntary disenrollment. The commenters requested that we retain the current regulation, which simply states that a PACE participant may voluntarily disenroll from the program without cause at any time. One commenter expressed concern that states' enrollment and disenrollment systems may not allow for disenrollment from a PACE program to be effective the first day of the following month if notice is given beyond a certain day of the

month. This commenter stated that while it is possible to disenroll a Medicare-only beneficiary effective the first day of the month following notification, disenrollment of Medicaid-only and dual-eligible PACE participants involves states' Medicaid systems, which may require notification to be provided in advance of a ''cutoff date'' in order for a disenrollment to be effective the first day of the following month. In these situations, the commenter stated, disenrollment requests received from Medicaid-only and dual-eligible PACE participants after a cutoff date may be delayed until the first day of the second month following receipt.

*Response:* We note that sections 1894(c)(5)(A) and 1934(c)(5)(A) of the Act state that PACE participants shall be permitted to voluntarily disenroll without cause at any time. After carefully considering the commenters' concerns, we respectfully disagree that concerns about state enrollment and disenrollment systems outweigh the need to protect participants by requiring POs to effectuate participant requests for disenrollment from the PO in an expeditious manner. While we appreciate the commenter's concern about state systems, we believe that it would be inappropriate to require that some PACE participants who wish to leave PACE remain enrolled for an additional month because of the inability of a state Medicaid agency to react to the participant's request in a timely manner. Delaying the effective date of a valid disenrollment request should not be the course of action when a participant's request for disenrollment is received toward the end of a month. We also note that imposing an early cutoff date creates unnecessary delays for participants who do not have Medicaid, even though the processing of their request does not involve any of the state systems issues described by the commenter. We believe establishing a policy of differing disenrollment effective dates based on PACE participants' eligibility for Medicaid and when they choose to submit the disenrollment request to the PO, would be challenging for POs to successfully implement and potentially confusing to participants. We also believe it would result in inequitable treatment among PACE participants. We further note that MA organizations and Medicare PDP sponsors have a longstanding requirement to effectuate voluntary disenrollment requests on the first day of the following month, regardless of when the request is received during the month or whether the beneficiary is eligible for Medicaid. We have operationalized this requirement for PACE by allowing participants to provide notice of voluntary disenrollment at any time and making that disenrollment effective on the first day of the month after the PO receives the notice. We believe that Medicare participants who have chosen to receive their Medicare health and drug benefits through PACE, instead of through an MA plan or a Medicare PDP, should not have their disenrollment delayed solely because they submit their request for disenrollment in the latter part of a month.

*Comment:* One commenter expressed support for the proposed requirement that POs ensure their employees or contractors do not steer or encourage disenrollment of PACE participants due to a change in health status. In addition, this commenter requested that we add ''functional, cognitive, or psychosocial'' as health status changes for which disenrollment should not be encouraged. In support of the comment, the commenter referenced the expansion of the non-discrimination provisions contained within § 460.40(a)(3) to include prohibitions on discrimination on the basis of ''functional, cognitive, or psychosocial status.''

*Response:* We appreciate the comment and agree that these sections of the PACE regulations should be consistent. However, as we explain in our discussion of § 460.40(a)(3) in section III.E.1 of this final rule, we inadvertently included the reference to ''functional, cognitive, or psychosocial status'' in the proposed rule and have restored the current language in this final rule. While we may consider revising the description of health status in future rulemaking, we are not doing so in this rule, and the reference to ''health status'' will remain in both § 460.40 and § 460.162. Therefore, we are finalizing this proposed change to § 460.162(c) without modification.

6. Involuntary Disenrollment (§ 460.164)

Section 460.164 specifies the conditions under which a PACE participant can be involuntarily disenrolled from a PACE program. The reasons for involuntary disenrollment are derived from sections 1894(c)(5)(B) and 1934(c)(5)(B) of the Act, additional statutory requirements (for example, the PACE program agreement is not renewed, or the participant no longer meets the state Medicaid nursing facility level of care requirements), and the PACE Protocol. We proposed to redesignate paragraphs (a) through (e) as paragraphs (b) through (f) and to add new paragraph (a) that specifies that a participant's disenrollment occurs after the PO meets the requirements in this section 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 sends a disenrollment notice on April 5, the disenrollment would be effective June 1–30 days after April 5 is May 5, and the first day of the next month after May 5 is June 1. We proposed to add this requirement to make it clear when a participant's involuntary disenrollment is effective. Additionally, we proposed to add this requirement to protect participants' due process, as our regulations and guidance do not currently include an advance notice requirement. We noted in the proposed rule that the PO must not send the disenrollment notice until the SAA has reviewed the involuntary disenrollment and determined that the PO has adequately documented acceptable grounds for disenrollment, as required by current paragraph (e) (proposed paragraph (f)). We stated that we believed 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, we noted in the proposed rule, a PO could notify a participant about an involuntary disenrollment late in the month and make the effective date of the involuntary disenrollment the first day of the following month, only a few days later. This would not allow sufficient time for a participant to contest the disenrollment or to effectively coordinate a transition to other care and services.

Section 460.164(a) currently states the reasons a participant may be involuntarily disenrolled from PACE. Paragraph (a)(1) states that the PO may involuntarily disenroll a participant for failing to pay, or to make satisfactory arrangements to pay, any premium due the PO after a 30-day grace period. As noted previously, we proposed to redesignate (a)(1) as (b)(1) and restructure the sentence 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. We explained in the proposed rule that we proposed the change because we believed the current sentence structure creates confusion as to whether the grace period applies to both payment of the premium ''and'' making satisfactory arrangements to pay. We noted that the 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. Satisfactory arrangements could be, for example, a participant's agreement to pay through installments, or agreement to pay within a specific time period.

We also proposed to redesignate paragraphs (a)(2) to (a)(6) as (b)(4) to (b)(8) and to add two additional reasons for involuntary disenrollment in new paragraphs (b)(2) and (b)(3). In paragraph (b)(2), we proposed new language that would permit involuntary disenrollment if the participant, after a 30-day grace period, fails to pay or make satisfactory arrangements to pay any applicable Medicaid spend-down liability or any amount due under the post-eligibility treatment of income processes as permitted under § 460.182 and § 460.184. Section 1934(i) of the Act, as well as §§ 460.182(c), 460.184, 460.152 and 460.154 pertain to these payment amounts. Under section 1934(i) of the Act and § 460.184(a), a state may provide for post-eligibility treatment of income for participants in the same manner as a state treats post-eligibility income for individuals receiving services under a Medicaid waiver under section 1915(c) of the Act. Section 460.182(c)(1) requires that the PO accept the Medicaid capitation payment as payment in full ''except'' for payment with respect to spend-down liability and post-eligibility treatment of income. Section 460.152(a)(1)(iv) and (v) requires that PACE staff explain specific information to the potential participant and his or her representative or caregiver, including any Medicaid spend-down obligation and post-eligibility treatment of income. Section 460.154(g) requires that a participant who is Medicaid eligible or a dual eligible be notified and required to acknowledge in writing that he or she may be liable for any applicable spend-down liability and amount due under the post-eligibility treatment of income process. We explained in the proposed rule that, operationally, a PO needs the ability to involuntarily disenroll participants based on nonpayment of these amounts. We noted that participants are obligated to pay these amounts as part of the PO's overall reimbursement for care and services provided through the program. Moreover, we stated that we understood that a participant's failure to pay these amounts can have a significant financial impact on the PO. Continued insufficient reimbursement to the PO on an ongoing basis could affect the PO's financial viability and its ability to continue operations. We explained that we have previously addressed this issue for many POs through approval of waivers, but we believed addressing it through a regulatory change is more efficient and is permitted under the PACE statutory authority. Moreover, we noted, as with any involuntary disenrollment, an involuntary disenrollment based on nonpayment of applicable Medicaid spend-down liability or any amount due under the post-eligibility treatment of income process must be reviewed by the SAA to determine that the PO has adequately documented acceptable grounds for disenrollment before it becomes effective.

In paragraph (b)(3), we proposed to add language that would permit involuntary disenrollment in situations where the participant's caregiver engages in disruptive or threatening behavior. We also proposed to redesignate current paragraphs (b)(1) and (b)(2) as paragraphs (c)(1)(i) and (c)(1)(ii), respectively, and to add new paragraph (c)(2) to describe what we consider to be disruptive or threatening behavior of a participant's caregiver.

Specifically, we proposed that a PACE participant may be involuntarily disenrolled from the PO if a participant's caregiver engages in disruptive or threatening behavior that jeopardizes the participant's health or safety, or the safety of the caregiver or others. We noted in the proposed rule that this would include any family member involved in the participant's care. We stated that we believed sections 1894(c)(5)(B) and 1934(c)(5)(B) of the Act, which state that a PO may not disenroll a participant except for engaging in disruptive or threatening behavior, as defined in such regulations (developed in close consultation with SAAs), could be read to include a caregiver. We also noted that the PACE Protocol listed as a basis for involuntary disenrollment that the participant ''experiences a breakdown in the physician and/or team-participant relationship such that the PO's ability to furnish services to either the participant or other participants is seriously impaired,'' which we believed could include disruptive or threatening behavior of a caregiver (64 FR 66300).

We explained in the proposed rule that, although we previously stated in the 2006 final rule (71 FR 71316) that we would not include as a basis for disenrollment the disruptive or threatening behavior of family members that are involved in the participant's care, as we gained more experience with PACE, we realized 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 to the participant in situations where the caregiver is engaging in threatening or disruptive behavior. We noted in the proposed rule that, given the variety of settings in which POs provide services, including the PACE center and the participant's home, there may be situations where the caregiver's disruptive or threatening behavior jeopardizes the health or safety of the participant, other PACE participants, staff, or visitors and it is not be feasible to establish alternative arrangements. We stated that we have already approved waivers for involuntary disenrollment, several of which address disruptive or threatening caregiver behavior. The requests for waivers have come from POs that have experienced situations in which their ability to safely and effectively care for participants is potentially compromised by the behavior of the participant's caregiver that jeopardizes the health or safety of others including other participants, staff, or visitors. We noted in the proposed rule that the proposed revision would obviate the need for those waivers, thereby reducing the burden on POs, states, and CMS.

We emphasized in the proposed rule that a PO must only pursue involuntary disenrollment of a participant based on a caregiver's behavior after it has engaged in efforts to resolve the situation and has documented all of those efforts. As set forth in current paragraph (e) (proposed paragraph (f)), all involuntary disenrollments require a review and final determination by the SAA before they can become effective, so as to ensure that the PO has adequately documented acceptable grounds for disenrollment. As set forth in § 460.168, when a PACE participant is disenrolled from the PO, the PO must facilitate a participant's enrollment into other Medicare or Medicaid programs for which the participant is eligible and must make sure medical records are available to the new providers. We explained in the proposed rule that this will help ensure that the participant receives needed care. We noted that we did not propose a similar change to § 460.164(b)(2) (proposed paragraph (c)(2)), which refers to involuntary disenrollment of a participant with decision-making capacity who consistently refuses to comply with his or her individual plan of care or the terms of the PACE enrollment agreement. 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.

A discussion of the public comments we received on our involuntary disenrollment proposals, and our responses to those comments, appears below.

*Comment:* Two commenters expressed support for our proposed clarification of the effective date of an involuntary disenrollment and the new proposed requirement for advance notice of the disenrollment. Another commenter expressed general support for these proposals but requested that we waive the 30-day advance notice requirement when a PACE participant is out of the PO's service area for more than 30 days without giving prior notice to the PO or obtaining approval from the PO.

*Response:* We appreciate the commenters' support for our proposals; however, we do not believe it would be appropriate to waive the advance notice requirement in circumstances where a participant is out of the PO's service area for a specified time period. We believe the proposed requirement to notify a participant in advance of the PO's decision to involuntarily disenroll the participant is an important protection for all participants, and while we agree that a participant's temporary absence from the service area may raise coverage challenges, we are concerned the lack of advance notice would result in some erroneous disenrollments, given that the participant may not have an opportunity to address any misunderstanding as to the participant's location before the disenrollment takes effect. In the absence of a requirement for advance notice, a PO potentially could issue a disenrollment notice on the last day of month and effectuate the disenrollment the next day. We also note that beneficiaries enrolled in MA plans, Medicare PDPs and Medicare cost plans are provided advance notice of an involuntary disenrollment. We believe that Medicare participants who have chosen to receive their Medicare health and drug benefits through PACE, instead of through an MA plan, Medicare PDP, or Medicare cost plan should have the same protection that advance notice of involuntary disenrollment affords.

*Comment:* One commenter recommended that CMS consider incorporating into the PACE regulations the grievance and appeals processes available to Medicaid managed care beneficiaries in involuntary disenrollment situations.

*Response:* While there are some similarities between the regulatory requirements for Medicaid managed care and PACE, they are not completely aligned with regard to how grievances and appeals are defined. We have established specific requirements for PACE regarding grievances (defined in § 460.120 as a complaint expressing dissatisfaction with service delivery or the quality of care furnished) and appeals (defined in § 460.122 as a participant's action taken with respect to the PO's noncoverage of, or nonpayment for, a service). Moreover, we have specified the limited reasons that a participant may be involuntarily disenrolled from PACE in § 460.164, and we require that before an involuntary disenrollment is effective, the SAA must review and determine in a timely manner that the PO has adequately documented acceptable grounds for the disenrollment. The state must provide an appeal avenue for both Medicaid and non-Medicaid participants related to involuntary disenrollments. Since Medicare-only participants do not have access to the State Fair Hearings process, states must develop an administrative review process for PACE participants who are not eligible for Medicaid to address appeals of involuntary disenrollments. And while the PACE regulations do not require the PO to establish an appeal process for an involuntary disenrollment, they are not prohibited from doing so. Because PACE already requires prior state review of a proposed involuntary disenrollment, as well as an avenue of resolution in response to a PO's action to involuntary disenroll a participant, we do not believe it is necessary to incorporate additional protections based on Medicaid managed care requirements.

*Comment:* One commenter expressed concern about the potential for POs to involuntarily disenroll participants considered ''difficult to serve'' based on the actions of their caregivers. However, the commenter noted that its concerns are mitigated by the expanded anti-discrimination protections proposed in § 460.40. The same commenter stated that PACE participants should not be held responsible for the actions of their caregivers unless the participant is involved to some extent in the disruptive behavior. Two commenters requested that we provide guidance to POs for instances in which a caregiver's behavior is viewed as potentially jeopardizing the health or safety of the participant, or the safety of others. Another commenter opposed involuntary disenrollment based on caregiver behavior, viewing such action as punitive to the participant and creating the potential for adverse health and safety issues. This commenter requested that POs be directed to find alternative arrangements instead of disenrolling the participant.

*Response:* We do not believe that involuntary disenrollment based on the disruptive behavior of a caregiver or family member should be contingent upon the involvement or encouragement of the participant. Due to the type of individual eligible for and enrolled in a PO (that is, frail elderly meeting a nursing home level of care) and the type of services needed, there is a greater prevalence of involvement by caregivers in most aspects of the participant's care. In addition, there may be participants who are entirely dependent on a caregiver or family member to obtain or arrange for care or services, leading to a greater potential for disruptive or threatening behavior on the part of the caregiver that hinders the PO's ability to provide services to the participant or to others or potentially jeopardizes the health or safety of the participant, or the safety of others. We believe such instances, while rare, may necessitate the involuntary disenrollment of the participant for the safety of the participant, the caregiver or others. We note that all PO requests for involuntary disenrollment due to disruptive or threatening behavior are reviewed for appropriateness by the SAA prior to the disenrollment occurring. We expect the PO to take appropriate action in a manner consistent with the legal requirements applicable to the jurisdictions in which it operates, including state laws relating to mandatory reporting of elder abuse, whenever abuse or neglect of a participant may have occurred. We expect POs to attempt alternative arrangements; however, as we stated in the proposed rule, we understand that is not always possible. We thank the commenters for their concern. Subsequent to the publication of this final rule, we will provide guidance to POs for instances in which a caregiver's behavior is viewed as potentially jeopardizing the health or safety of the participant, or the safety of others.

Regarding the comment referring to expanded anti-discrimination protections, as we discussed previously in sections III.E.1 of this final rule, we inadvertently included a reference to ''functional, cognitive, or psychosocial status'' in § 460.40(a)(3) in the proposed rule, even though our intention was solely to redesignate the paragraph, and we have restored the existing language in this final rule.

*Comment:* One commenter requested that we establish a process for expedited

SAA review of a PO's request for involuntary disenrollment on the basis of threatening or disruptive behavior and that this process not exceed 30 days. The same commenter suggested that CMS provide advance notice to PACE participants when an involuntary disenrollment request is filed with the SAA and that the PO begin transferring the participant to fee-for-service (that is, non-PACE) providers pending final SAA determination.

*Response:* We agree that advance notification to participants of the potential for involuntary disenrollment based on caregiver behavior may be helpful; however, we did not propose a new requirement for a notice that would be issued to the participant when the PO submits a request for involuntary disenrollment to the SAA. We also did not propose the creation of a new option for an expedited SAA review of requests for involuntary disenrollment or a new process in which participants are transferred to non-PACE providers prior to the SSA approving the request for involuntary disenrollment. While we believe these recommendations are outside the scope of this rule, we will take these comments under consideration for future subregulatory guidance or rulemaking.

*Comment:* Commenters were supportive of our proposal to include as a basis for involuntary disenrollment the disruptive or threatening behavior of family members that are involved in the participant's care and involuntary disenrollment based on nonpayment of applicable Medicaid spend-down liability or any amount due under the post-eligibility treatment of income process.

*Response:* We appreciate the support expressed by the commenters to establish these additional bases for involuntary disenrollment. After considering the comments, we are finalizing those proposed changes, as well as our other involuntary disenrollment proposals without modification.

7. Effective Date of Disenrollment (§ 460.166)

Section 460.166 is currently titled ''Effective date of disenrollment;'' however, it focuses on the PO's responsibilities when disenrolling a participant. Therefore, we proposed to change the title to ''Disenrollment responsibilities'' to better describe the subject of this section.

We received no comments on this proposal, and therefore, we are finalizing it without modification.

8. Reinstatement in Other Medicare and Medicaid Programs (§ 460.168)

Section 460.168 describes the PO's responsibility to facilitate a participant's reinstatement in other Medicare and Medicaid programs after disenrollment. Section 460.168(a) states that a PO must make appropriate referrals and ensure that medical records are made available to new providers in a ''timely manner.'' To ensure POs interpret ''timely manner'' uniformly, we proposed to change ''in a timely manner'' to ''within 30 days,'' which would help ensure a smooth transition for participants. We proposed 30 days because we believed this would balance the need to give the PO adequate time to gather the medical records, make copies, and deliver them to the 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.

*Comment:* One commenter expressed support for our proposal to require POs to make appropriate referrals and ensure medical records are made available to new providers ''within 30 days,'' as opposed to in a ''timely manner.'' Another commenter requested that we clarify the actions to which the proposed timeframe refers.

*Response:* We did not propose any changes to the actions the PO must take to facilitate a participant's reinstatement in other Medicare and Medicaid programs after disenrollment. We believe the actions to which the 30-day timeframe applies are adequately specified in the regulation; just as the current timeliness requirement applies to both making appropriate referrals and ensuring medical records are made available to new providers, the PO will be expected to carry out both of those actions ''within 30 days'' once the final rule takes effect. We are finalizing this provision as proposed.

*K. Subpart J—Payment*

1. Medicaid Payment (§ 460.182)

Section 1934(d) of the Act requires a state to make prospective monthly capitated payments for each PACE program participant eligible for medical assistance under the state plan. The capitation payment amount must be specified in the PACE program agreement and be less, taking into account the frailty of PACE participants, than the amount that would otherwise have been paid under the state plan if the individuals were not enrolled in a PACE program. As we explained in the proposed rule, there is no national Medicaid rate-setting methodology for PACE; rather, each state that elects PACE as a Medicaid state plan option must develop a payment amount based on the cost of comparable services for the state's nursing facility-eligible population. Generally, the amounts are based on a blend of the cost of nursing home and community-based care for the frail elderly. The monthly capitation payment amount is negotiated between the PO and the SAA and can be renegotiated on an annual basis.

We implemented the PACE statutory requirements for Medicaid payment in § 460.182. Section 460.182(b) states that the monthly Medicaid capitation payment is negotiated between the PO and the SAA and specified in the PACE program agreement, and the amount meets certain criteria set forth in paragraphs (b)(1) through (b)(4). Consistent with the revisions to § 460.32(a)(12), we proposed 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. We explained in the proposed rule that as a result of changes to the methods states are using to determine capitation rates, which can result in varied payment based on frailty of the population and performance incentive payments, we have found that specifying the capitation amount in the program agreement is sometimes operationally impractical. Additionally, we noted in the proposed rule, because many states update their PACE Medicaid capitation rates annually based on the state fiscal year, there are operational challenges associated with updating the PACE program agreement appendices to reflect changes to the Medicaid rates. We stated that we believed providing the option of including the state's methodology for calculating the Medicaid capitation payment amount is consistent with the statutory requirement in section 1934(d)(2) of the Act that the program agreement specify how the PO will be paid for each Medicaid participant, and we believed it would result in less burden for POs, states and CMS by eliminating the frequency of updates to the PACE program agreement to reflect the routine changes to the PACE Medicaid capitation rates.

We also proposed to redesignate paragraphs (b)(3) and (b)(4) as paragraphs (b)(4) and (b)(5) and add a new paragraph (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. Current paragraph (b)(1) requires that the

Medicaid rate be less than what otherwise would have been paid if the participants were not enrolled in PACE, which in essence establishes an upper bound under which the rate must fall. We explained in the proposed rule that while current paragraph (b)(2) also requires that the rate take into account the comparative frailty of PACE participants, the regulation does not require that the 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. We noted in the proposed rule that we proposed the new language to ensure that the Medicaid rate paid under the PACE program agreement is not only less than what would otherwise have been paid outside of PACE for a comparable population, but is also sufficient for the population served under the PACE program, which we believed 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. We proposed that the monthly capitation amount be consistent with efficiency, economy, and quality of care. We explained in the proposed rule that, by efficiency and economy, we meant that the payment amount must reflect that POs bring more efficiencies to the administration, management and oversight of participant care because they are singularly 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. We noted that while the efficiencies of providing and coordinating all of a participant's care can result in lower expenditures as compared to a more fragmented payment system with multiple providers and entities providing different aspects of an individual's care, the Medicaid monthly capitation amount must also enable the PO to ensure participant access to quality care and services to meet the participant's needs. We stated that failure to provide adequate reimbursement to POs could negatively affect participant care through reduced care and service authorizations, as well as limit resources for the PO to promote program goals such as quality of care, improved health, community integration of participants, and cost containment, where feasible.

Additionally, we solicited comments about other rate methodologies we may consider requiring for Medicaid capitation payment amounts for PACE. We requested input to determine 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. We provided as an example that Medicaid rates for many of the state financial alignment demonstrations require actuarially sound rates. We noted, however, that any change to the PACE rate setting requirements would need to ensure that the rates are still less than the amount that would otherwise have been made under the state plan if individuals were not enrolled in PACE and be adjusted to take into account the comparative frailty of PACE enrollees, which is required under section 1934(d)(2) of the Act. We did not propose changes to the rate methodology for Medicaid capitation payments, but we stated that we would use public comment to inform possible future PACE rulemaking concerning Medicaid capitation payments.

The following is a summary of the public comments we received on the proposed provisions regarding Medicaid payment and our responses to comments.

*Comment:* All commenters supported the proposal to incorporate the state's Medicaid rate methodology *or* the Medicaid rates into the PACE program agreement instead of requiring the actual rates. Most commenters supported the proposal without reservation. However, one commenter stated that while the commenter supports the Medicaid rate methodology proposal, it seems to remove the incentive for the state to negotiate the Medicaid rates in a timely manner.

*Response:* We appreciate the support for this proposed change. In response to the comment expressing concern that states will have less incentive to update and negotiate their rates in a timely manner, we will take this into consideration when issuing updated guidance to states regarding the Medicaid rate setting process.

*Comment:* All commenters supported the proposal to add the requirement that Medicaid PACE capitation rates be sufficient and consistent with efficiency, economy and quality of care. However, two commenters recommended that CMS use alternate language instead of ''sufficient'', such as ''reasonable and appropriate'' or ''reasonable, appropriate and attainable'', which is part of the standard in § 438.4(a) for actuarially sound capitation rates in Medicaid managed care. One commenter recommended defining ''sufficient'' in regulation to mean 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. Two commenters also requested details or guidance on how the ''lower bound'' would be calculated. Two commenters suggested requiring sufficient language in the rate method description to enhance transparency of the Medicaid rate setting process. Two commenters recommended requirements to ensure Medicaid rates take into account the full financial risk for all Medicaid covered services, including nursing home care, without a restriction or adjustment for length of stay. One commenter recommended that the final rule promote use of experience and risk based methodologies in general, and support state flexibility in tailoring rate setting methods to reflect state circumstances. Another commenter recommended allowing direct use of appropriate adjusted experience from Medicaid managed LTC programs in addition to or in place of FFS experience or PACE experience.

*Response:* We appreciate the overall support for this proposed change. In response to the commenter that recommended we modify language in the final rule to clarify that rates should be actuarially sound, we are not able to require that PACE rates be actuarially sound because actuarially sound rates could exceed the amount that was otherwise paid by the state, if the individuals were not enrolled in PACE, and PACE rates are required by statute to be less than the amount that would have otherwise been paid if participants were not in PACE. In response to the commenters that recommended alternative language to ''sufficient and consistent with efficiency, economy and quality of care'', which is terminology that governs Medicaid fee-for-service payments at section 1902(a)(30)(A) of the Act, and instead recommended language consistent with established standards used in Medicaid managed care, we agree this standard would be more appropriate because PACE as a capitated model is more aligned with Medicaid managed care than Medicaid fee-for-service. In response to commenters' concerns regarding transparency of the state's rate method,

and that rates take into account the full financial risk that POs assume, we will take that into consideration when issuing updated guidance to states regarding the Medicaid rate setting process. In response to the commenter questioning how the ''lower bound'' will be defined, we did not intend to establish or define a specific lower bound for PACE Medicaid rates, but would expect the state to be able to demonstrate that the Medicaid rates comply with regulatory requirements. In response to the comment regarding state use of Medicaid managed LTC experience in development of PACE rates, the current regulation requires that the Medicaid rates be less than the amount that would otherwise been paid under the state plan if the participants were not enrolled in PACE, among other requirements. That amount is not limited to a fee-for-service comparable population, and states are not prohibited from using Medicaid managed care data in determining the amount that would otherwise have been paid, but they must be able to demonstrate that the amount meets the existing PACE requirements. Recognizing that more states will be using managed care experience for their comparable population, we will take that into consideration when issuing updated guidance to states regarding the Medicaid rate setting process in PACE. We appreciate the overall support for the proposed changes. While we are finalizing § 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, we have decided not to finalize the proposed language that rates be sufficient and consistent with efficiency, economy and quality of care. However, we appreciate all of the comments and feedback and will take this input into account as we consider any changes during future rulemaking.

*Comment:* Regarding alternative rate methodologies for PACE Medicaid payments, some commenters suggested: Using Grade of Membership methodology to identify a long-term-care admission cohort; permitting a ''tiered'' rate structure that Medicare-only individuals would be required to pay based on services provided under the program; requiring actuarial certification of rates; requiring that rates related to LTSS be consistent across Medicaid and PACE; and that CMS develop a workgroup with stakeholders including the National PACE Association and POs regarding alternate methods for rate setting. Two comments related to the Medicare PACE capitation amounts and suggested: That Medicare rates for POs be consistent with Medicare Medicaid Plans (MMP) or Dual Special Needs Plans (DSNP) to create a level playing field; and that changes to PACE Medicare rates be made to align with MA rules.

*Response:* We appreciate the feedback provided in response to our request for comments about other rate methodologies that may be applied to PACE Medicaid payments. While we did not propose changes to the rate methodology for Medicaid capitation payments, we will use the public comments received to inform possible future PACE rulemaking concerning Medicaid payment. We did not propose any changes to the Medicare payment requirements under § 460.180, and therefore, we believe the recommendations for changes to the Medicare PACE rates are outside of the scope of this rule.

*L. Subpart K—Federal/State Monitoring*

1. Monitoring During Trial Period (§ 460.190) and Ongoing Monitoring After Trial Period (§ 460.192)

Sections 1894(e)(4)(A) and 1934(e)(4)(A) of the Act require the Secretary, in cooperation with the SAA, to conduct a comprehensive annual review of the operation of a PO during its trial period in order to assure compliance with the requirements of sections 1894 and 1934 of the Act and PACE regulations. The trial period is defined as the first 3 years of the PO's contract with CMS and the SAA. Sections 1894(e)(4)(A) and 1934(e)(4)(A) of the Act further provide that the review must include: An on-site visit; a comprehensive assessment of the PO's fiscal soundness; a comprehensive assessment of the PO's capacity to provide PACE services to all enrolled participants; a detailed analysis of the PO's substantial compliance with all significant requirements of sections 1894 and 1934 of the Act and PACE regulations; and any other elements the Secretary or the SAA considers necessary or appropriate. Sections 1894(e)(4)(B) and 1934(e)(4)(B) of the Act provide that the Secretary, in cooperation with the SAA, must continue to conduct reviews of the operation of the PO after the trial period as may be appropriate, taking into account the performance level of a PO and compliance of a PO with all significant requirements of sections 1894 and 1934 of the Act and PACE regulations. Sections 1894(e)(4)(C) and 1934(e)(4)(C) of the Act provide that the results of the reviews must be reported promptly to the PO, along with any recommendations for changes to the PO's program, and made available to the public upon request.

Sections 460.190 and 460.192 set forth the requirements for monitoring during and after the trial period, respectively. These regulations currently incorporate requirements from the PACE Protocol that are more specific than those provided in statute, in that § 460.190(b)(1) details specific activities that must occur onsite during the trial period reviews, and § 460.192(b) requires that, after a PO's trial period ends, ongoing reviews be conducted onsite at least every 2 years. We proposed to revise these provisions of the existing regulations.

As we explained in the proposed rule, in the 15 years since the initial PACE regulations were established, the PACE program has flourished and we have gained significant program experience with respect to oversight and monitoring of POs. We noted in the proposed rule that we no longer believed that the activities listed in § 460.190(b)(1)(i) through (b)(1)(v) must be performed while onsite at the PACE location; technology affords us the opportunity to complete these tasks remotely. For example, we have implemented the use of webinar technology in the performance of similar program audits of Medicare Advantage organizations and Part D sponsors. This technology allows the entity being reviewed to provide CMS access to information on its computer systems in real time, in a secure manner. It also allows reviewers to interact with the entity being reviewed and its staff, while not being physically present in the building with them. We stated in the proposed rule that the use of this technology has saved significant resources in travel dollars and staff downtime (experienced while they are traveling). Therefore, we proposed to delete the list of specific activities that may be performed as part of an onsite visit as currently set forth in the paragraphs located in § 460.190(b)(1)(i) through (b)(1)(v).

In addition, we proposed revisions to the language at § 460.190(b)(1) and a new paragraph in § 460.190(b)(2) to more closely mirror the text of statute. We noted in the proposed rule that the proposed language retains the obligation that CMS conduct an onsite visit to observe the PO's operations. However, it affords reviewers the flexibility to conduct other portions of the review remotely. We explained that greater flexibility to conduct portions of the review remotely would allow our reviews of POs to gain some of the same

efficiencies that CMS currently achieves through the use of web-based technologies in other programs. Specifically, we proposed in the revised § 460.190(b)(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 proposed a separate requirement in the 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 Act and the PACE regulations, which may include review of marketing, participant services, enrollment and disenrollment, and grievances and appeals. We proposed to retain the language found in current (b)(2), (b)(3), and (b)(4), but proposed to redesignate these as (b)(3), (b)(4), and (b)(5).

Section 460.192(b) of the current regulations establishes the obligation for continued oversight after the trial period, including the requirement for an onsite review of every PO every 2 years. We explained in the proposed rule that as the PACE program has grown, and with it the number of POs, the amount of resources spent conducting both trial period and on-going audits of POs has significantly increased. We stated that we must balance the responsibilities of ensuring that all of our beneficiaries are receiving quality care with our duty to effectively manage our resources and ensure proper oversight over all of the programs we manage. Sections 1893 and 1894 of the Act do not require the current level of monitoring.

Consequently, we noted in the proposed rule that we believed that the frequency of ongoing reviews of POs beyond their trial period should occur based on a risk assessment that takes into account the PO's performance level and compliance with the significant requirements of sections 1834 and 1934 of the Act and the PACE regulations. Therefore, we proposed to delete the language in § 460.192(b) that requires onsite review every 2 years and replace it with that requirement that CMS, in cooperation with the SAA, will conduct reviews of the operations of POs as appropriate, by utilizing a risk assessment as the means of selecting which POs will be audited each year. We stated in the proposed rule that this risk assessment would rely largely on the organization's past performance and ongoing compliance with CMS and state requirements. However, we proposed that the risk assessment also take into account other information that could indicate a PO needs to be reviewed, such as participant complaints or access to care concerns. This would mirror our approach in selecting organizations for audit in other programs such as the MA and Part D programs, which is a data driven, risk-based approach. We noted that this risk assessment would utilize important measures specific to PACE, as determined by us including, but not limited to, length of time between audits, past performance, and other data measures, such as grievances and/or self-reported adverse events, also known as PACE Quality Data, as necessary. We stated that we believe using MA and Part D is an appropriate model on which to base PACE audits, because like in MA and Part D, a PO is responsible for providing a participant's benefits in accordance with our regulations. We also explained that we have discovered through the MA and Part D programs that sponsors have varying degrees of compliance and that auditing organizations based on risk allows CMS to focus on those organizations that require closer scrutiny. Similarly, program experience has shown that POs also have varying degrees of compliance; therefore, we noted that we believed this will be a useful tool in selecting organizations for audit and will allow continued oversight and monitoring in the PACE program, with better targeting of resources based on the relative risk each organization presents.

2. Corrective Action (§ 460.194)

Section 460.194(a) requires a PO to take action ''to correct deficiencies identified during reviews.'' However, as we stated in the proposed rule, there has been some uncertainty as to which circumstances trigger the requirement that a PO take action to correct deficiencies. We proposed to revise this regulation to clarify for POs the range of circumstances under which CMS or the SAAs may identify deficiencies that would require action by the POs to correct those deficiencies. We proposed to change § 460.194(a) to state that a PO must take action to correct deficiencies identified by CMS or the SAA as a result of the following:

- Ongoing monitoring of the PO;
- Reviews and audits of the PO;
- Complaints from PACE participants or caregivers; and
- Any other instance CMS or the SAA identifies programmatic deficiencies requiring correction.

We proposed this change to specify that corrective actions will be required to address deficiencies identified by CMS or the SAA through any of these mechanisms.

3. Disclosure of Review Results (§ 460.196)

As we stated in the proposed rule, PACE participants are a frail and vulnerable population, and we recognized that in some cases they may be unable to fully grasp the nature of our review results and use them to make decisions about their healthcare. Our reviews measure the PO's compliance with a variety of CMS requirements, such as the ability of the PO to deliver medically necessary healthcare and medications to their participants. Currently, the regulations require that POs make their review results available in a location that is readily accessible to their participants, without mention of accessibility to other parties. However, we explained in the proposed rule that we believed that not only participants but also their family members, caregivers, or authorized representatives should have access to that information in order to better inform their decisions about the participants' healthcare. Therefore, we proposed to amend § 460.196(d) to ensure that POs make review results 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, because we believed they should be fully aware of the PO's performance and level of compliance with statutory and regulatory requirements. We also encouraged POs to make review results available to other potential participants and the public, for example, by releasing a summary of the reports online. We stated in the proposed rule that posting comprehensive review results online would satisfy PO requirements under § 460.196(d).

The following is a summary of the public comments we received on the proposed provisions regarding federal and state monitoring and our responses to comments.

*Comment:* The majority of commenters supported our proposal to no longer mandate an onsite audit every 2 years for every PO following the 3-year trial period. However, while supportive of our proposal to change how often we audit POs following the trial period, multiple commenters were concerned with allowing POs to go too long without an audit. These commenters thought that CMS should set an outer limit (or maximum length of time) that a PO can go without having an audit. These commenters referenced the frail population in PACE as a reason to ensure that POs get an audit on a regular basis. These commenters

suggested a maximum length of time between audits ranging from 3 to 6 years.

*Response:* We agree with the commenters that there should be a defined length of time that a PO can go without an audit following the trial period. We do not believe that a maximum time limit needs to be implemented through regulation as it is an internal decision and we need operational flexibility to modify this timeframe when necessary based on how the PACE program changes through the years. Therefore, we intend to implement internal guidelines to ensure that POs are audited with an appropriate frequency, but not modify the proposed regulatory text. Additionally, we believe by utilizing a risk assessment for audit selection, we will be able to appropriately safeguard this frail population by targeting, as often as necessary, those POs that CMS believes may present a higher risk to participants' health and safety.

*Comment:* A few commenters, although not against us finalizing the proposed regulatory changes to monitoring requirements, urged caution in expanding the time between PACE audits following the trial period. One commenter mentioned that increasing the time between audits would place a heavier burden on SAAs. Another commenter mentioned that if a PO is embarking on an expansion, the frequency of monitoring should increase during this period of expansion.

*Response:* We appreciate these commenters' concerns. We understand that some SAAs may choose to audit POs more frequently if we decide not to audit a particular PO for a number of years. We believe this is an important part of our partnership with the SAAs, and encourage states to monitor POs as often as they believe necessary. While we may not continue to audit all organizations as frequently after the trial period as we did prior to the implementation of this regulation, we will continue frequent account management monitoring and quality reporting for all POs. We believe that this account management monitoring, along with our risk assessment and audits, will help us maintain an appropriate level of oversight in PACE. We also appreciate the comment regarding audits when POs are embarking on an expansion, and we will retain authority to audit POs more frequently if needed.

*Comment:* Two commenters expressed concern with reducing the number of onsite audits conducted by CMS after the trial period. One commenter said reducing the number of onsite audits would be eliminating the tools that are proven to work in assessing quality of care. The other commenter suggested that if we audit less frequently, we should collect documentation from the PO more frequently to compensate.

*Response:* While we understand these commenters' concerns, we are confident that we will still conduct effective oversight over POs even if we no longer require onsite visits at least every 2 years. POs that present a higher risk to participants will still be audited on a more frequent basis. Only those organizations that are assessed to be a lower risk will go longer between reviews. Additionally, while we may audit an organization less frequently, POs are still subject to routine account management monitoring and quality reporting. Additionally, the SAA may audit or monitor POs as they see fit, including requesting documentation from POs between audits.

*Comment:* Several commenters requested clarification on the risk assessment CMS intends to use to select POs for audits. Commenters encouraged CMS to be transparent in how we select POs, including what performance measures we will be using for the risk assessment. Some commenters wanted confirmation that the risk assessment would not be arbitrary and would utilize reasonable standards. Another commenter wanted clarification on whether the risk assessment would be consistent from region to region. Lastly, one commenter requested that grievances be considered in whatever risk assessment is created.

*Response:* We appreciate these commenters' questions and comments concerning the risk assessment. We believe that by utilizing a data based risk assessment we will be able to appropriately target POs for audit. While we will strive to be transparent in factors or performance standards we will use for our risk assessment, this is an internal tool that will likely change slightly every year based on what CMS PACE subject matter experts believe is important. At a minimum, this assessment tool will likely review data related to grievances, complaints and access to care and take into account when the PO was last audited. Additionally, the risk assessment will likely include measures related to performance level of the PO and any referrals made by either CMS or the SAA. While we do not intend to publish the exact measures utilized in the risk assessment, we anticipate including information in an annual audit report that will discuss the risk assessment for PO audits at a high level, as well as the POs selected for audit in a given year. The annual report may also include summarized audit results, including, common conditions/findings cited and any audit scores applied based on conditions cited. The annual report will be released by us each year through an HPMS memorandum to the industry.

*Comment:* We received several comments on our proposed use of technology for conducting audits, specifically using webinars to audit a PO when we would not be onsite for the audit. Most of the commenters expressed support for our proposal to use technology to conduct audits. These commenters warned, however, that while the use of technology is good, POs are small and have limited resources, and reminded us that not all organizations will be equipped to handle webinar audits in the same way.

*Response:* Since PACE is a direct care model, there are times when audits must be conducted onsite. However, allowing the use of webinar technology would allow us to conduct comprehensive reviews of a PO's ability to provide care and services, through review of participant health records, appeals, grievances, and other key program areas. We recognize that most POs are small, and some do not have the sophisticated electronic systems of some larger organizations. Auditors will work within the systems that POs have when conducting audits.

*Comment:* One commenter questioned if webinar use would mean that auditors would no longer need remote access to POs' systems, like electronic health records.

*Response:* While we believe that the use of webinars would reduce the instances where auditors may need remote access to review participant records, there may still be instances where remote access is needed. Among other factors, because POs are direct care models, auditors are sensitive to the amount of time PO staff is required to spend conducting the audit and away from providing care to participants. Therefore, auditors may determine that conducting portions of the audits through remote access, rather than through a webinar, would be more beneficial to the PO and participants.

*Comment:* One commenter opposed our proposed removal of specific program elements from the regulation that might be reviewed while onsite during the trial period audits, specifically marketing, enrollment and disenrollment procedures, participant services, grievances and appeals.

*Response:* We appreciate this commenter's concerns, however, the removal of the specific elements from

the regulation text does not mean we will no longer be reviewing those elements, either during the trial period or during routine audits. While we are eliminating the reference to specific portions of the regulation, it remains our intent that audits are comprehensive reviews of a PO's compliance with PACE regulations. A key part of that review will be focused on participant records, and all other services relating to a participant's experience and access to care which may continue include review of marketing, participant services, enrollment and disenrollment procedures, and grievances and appeals.

*Comment:* One commenter questioned if CMS intends to release a new PACE manual and audit guide after this rule is finalized.

*Response:* After publication of this final rule, we intend to update the PACE manual to reflect the new rules, including the monitoring section of the manual. The PACE audit protocol (guide) was revised in 2017 and was posted for public comment through the Paperwork Reduction Act process. Following publication of the final rule, both the PACE audit protocol and internal auditor instructions will be assessed and updated as needed. The current PACE audit protocol is available at *https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PACE_Audits.html.*

*Comment:* One commenter expressed a concern with for-profit POs, and recommended for-profit organizations should be audited more often than not-for-profit organizations.

*Response:* For purposes of auditing following the trial period, POs that are selected for audit will be selected using a risk assessment tool that assesses a number of factors related to PACE performance. We do not intend to select POs based on for-profit or not-for-profit status.

*Comment:* One commenter requested that we make auditors aware of the differences between MA and Part D plans and POs.

*Response:* We agree that PACE is a unique program as both a payer and direct care provider. PACE auditors are trained to understand the unique nature of the PACE program prior to conducting any audits.

*Comment:* One commenter encouraged CMS to conduct transparent exit interviews at the conclusion of a PO audit.

*Response:* We agree that we should always strive to be transparent with our audits, including conducting exit conferences to discuss conditions of non-compliance with the PO prior to auditors concluding the audit. Our audit process was revised in 2017 and the new audit protocol for PACE was approved under the Paperwork Reduction Act approval process. This new audit process includes conducting exit interviews following the CMS audit in order to ensure we are transparent regarding the potential non-compliance noted during the review.

*Comment:* Multiple commenters were supportive of our proposed revision to the requirements for disclosure of the results of PO reviews. Several of these commenters supported our proposal that POs be responsible for making the review results available for examination in a place that is readily accessible to not only participants, but also their family members, caregivers, and authorized representatives. A few commenters, while supportive of the disclosure requirements, thought CMS should be responsible for posting the results of the review so that all consumers can make an informed decision about their PACE program.

*Response:* We agree that disclosing audit results to more than just participants is important, particularly for family members, caregivers, and authorized representatives that are responsible for making informed decisions regarding appropriate health care. We appreciate commenters' support for our proposal to require POs to make these disclosures. We also appreciate the benefits of CMS reporting some results at a national level in order to continue promoting improvements across the industry, and allowing participants and others to make informed decisions.

We published our first annual audit report in 2018 which summarized audit results from the 2017 audit year, including common conditions/findings, and provided a general overview of the audit structure. That report is available at *https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PACE_Audits.html.* As noted previously in this final rule, we anticipate this report will continue to be released to the industry via HPMS annually and will include not only summarized information regarding common conditions, but information specific to individual POs as well, including audit scores.

*Comment:* Two commenters commented on the format of the disclosed review results. One commenter encouraged CMS to make reports as reader friendly as possible in order to aid participants and family members with understanding the results. The other commenter requested that results be published in a standardized manner to help participants and caregivers understand them.

*Response:* We agree with the commenters that reports and results should be standardized and in an easily readable format. During our audit redesign, we developed standardized reports and will continue to refine them based on continued audit experience and PO feedback.

*Comment:* One commenter encouraged CMS to not only disclose audit results publicly, but also create a rating system for POs based on quality measures to help participants and their caregivers in making informed decisions.

*Response:* We thank the commenter for the suggestion. We believe requiring POs to make audit results available to caregivers will help caregivers, participants and their families make informed decisions about participants' care. While we currently score POs' performance in audits, and publish those scores in an annual report, we do not intend to develop a separate rating system due to the unique nature and structure of POs around the country.

*Comment:* Several commenters, while supportive of POs disclosing audit results to participants and their families, caregivers, and authorized representatives, were concerned that audit reports are too negative. These commenters stated that by focusing only on a PO's deficiencies, the disclosure of these results skew or bias a participant or a participant's caregiver when making a decision about care. These commenters stated that the disclosure of results should focus on positive aspects of the organization, as well as deficiencies.

*Response:* We understand the concern presented by these commenters. CMS audits are intended to assess a PO's compliance with PACE regulations and manual guidance. Our audits focus on those areas in the PO that are not in compliance and need corrective action implemented. Our audits also focus on the participant experience and access to care. POs are currently required to make the results of these reviews readily available to participants; however, we believe that it is important that caregivers, family members, and authorized representatives are also able to see these results.

*Comment:* Some commenters offered their support for our proposed modifications to clarify the circumstances when a PO must take action to correct deficiencies identified by CMS or the SAA.

*Response:* We appreciate the support for this proposal.

After considering the comments, we are finalizing the changes to the federal and state monitoring requirements as proposed.

*M. Subpart L—Data Collection, Record Maintenance, and Reporting*

1. Maintenance of Records and Reporting of Data (§ 460.200)

In accordance with sections 1894(e)(3)(A) and 1934(e)(3)(A) of the Act, § 460.200 requires POs to collect data, maintain records, and submit reports, as required by CMS and the SAA. Section 460.200(f)(1) states that a PO must retain records for the longest of the following periods: (i) The period of time specified in state law; (ii) 6 years from the last entry date; or (iii) for medical records of disenrolled participants, 6 years after the date of disenrollment. We proposed to change the requirements in paragraphs (f)(1)(ii) and (iii) from 6 years to 10 years for consistency with the statute of limitations under the False Claims Act (31 U.S.C. 3731(b)(2)). For enrollee records, under § 460.200(f)(1)(ii) and (iii), the 10-year requirements would apply only to records of new and existing enrollees in the PO. We explained in the proposed rule that Medicare Advantage requirements at § 422.504(d), Medicare Part D requirements at § 423.505(d), and other CMS programs' record retention requirements, all conform to the statute of limitations for the discovery of violations under the False Claims Act. We also noted that POs that offer qualified prescription drug coverage currently must comply with the Medicare Part D record retention requirement in § 423.505(d). In addition, we stated that the 10-year record retention policy is also consistent with recordkeeping requirements under the Medicaid Drug Rebate Program (§ 447.510(f)). We proposed to extend the 10-year record retention requirement to all PACE records for consistency with these programs and to ensure we have proper oversight for investigating the complex payment and other relationships associated with delivery of Medicare and Medicaid benefits under the PACE program.

The following is a summary of the public comments we received on the proposed provisions regarding data collection, record maintenance and reporting, and our responses to comments.

*Comment:* One commenter supported our proposal to change the PACE record retention requirement from 6 to 10 years.

*Response:* We thank the commenter for its support.

*Comment:* One commenter requested that CMS require POs to collect and report participant data for several ''sociodemographic'' factors, including age, race, ethnicity, primary language, gender identify, sexual orientation, in connection with PACE quality policies.

*Response:* We do not currently collect this information from POs, but will take this suggestion into account as we consider future subregulatory guidance or rulemaking on PACE quality requirements.

As a result of the comments, we are making no changes to our proposal and are finalizing the modifications to § 460.200 as proposed.

## IV. Provisions of the Final Rule

For the most part, this final rule incorporates the provisions of the proposed rule. Those provisions of this final rule that differ from the proposed rule are as follows:

In section III.C.4. of this final rule, Subpart B—PACE Organization Applications and Waivers, we are clarifying the timeframes for applications at § 460.20(c)(2).

In section III.C.6. of this final rule, we are clarifying the PACE waiver submissions process at § 460.26.

In section III.F.10. of this final rule, we are revising the text to specify expectations for agent/broker training at § 460.82(e)(4).

In section III.G.3. of this final rule, regarding the IDT for PACE participants, we are revising § 460.98(c)(1) to refer to ''primary care, including services furnished by a primary care provider as defined in § 460.102(c) and nursing services''.

In section III.G.3. of this final rule, we are not finalizing our changes to § 460.104(d)(2) as proposed and will maintain the current provision which requires that the appropriate members of the IDT, as identified by the IDT, must conduct the in-person assessment. We are however revising § 460.104(d)(2) to specify that unscheduled reassessments may be performed using remote technology in certain circumstances. Specifically, when a participant or his or her designated representative makes a request to initiate, eliminate or continue a particular service, the appropriate members of the IDT, as determined by the IDT, may use remote technologies to conduct unscheduled reassessments when the IDT determines that the use of remote technology is appropriate and the service request will likely be deemed necessary to improve or maintain the participant's overall health status and the participant or his or her designated representative agrees to the use of remote technology.

In section III.F.3. of this final rule, we are finalizing the provisions related to the compliance oversight program as proposed at § 460.63 in part. We are not finalizing the provision that would require POs to audit and monitor their operations, but we are finalizing the provision that would require POs to identify, respond to and correct non-compliance and fraud, waste and abuse.

In section III.F.2. of this final rule, we are not finalizing the proposal to add a new § 460.62(a)(8) specifying that the governing body of the PO must have full legal authority and responsibility for adopting and implementing the compliance oversight program.

In section III J.1. of this final rule, we are revising § 460.182(b)(3) to require that the Medicaid capitation rate provides for reasonable, appropriate and attainable costs that are required under the PACE program agreement for the operation of the PO for the time period and the population covered.

## V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*) we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comments on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

On August 16, 2016 (81 FR 54692 through 54697), we solicited public comment on each of these issues for the following sections in the proposed rule that contained information collection requirements. As indicated below, we received comments pertaining to the IDT under § 460.102. Otherwise, no PRA-related comments were received and the provisions were adopted as proposed.

*A. Wage Estimates*

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2016 National Occupational Employment and Wage Estimates for all salary estimates (*www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 2 presents the mean hourly wage, the cost of fringe benefits and support costs (calculated at 100 percent of salary), and the adjusted hourly wage for the occupation code, 29–9000, ''Other Healthcare Practitioners and Technical occupations,'' in the occupational category 29–0000, ''Healthcare Practitioners and Technical Occupations.'' This code was selected since it includes PO, CMS and State staff working in healthcare but who do not have specialist or technical specialist titles.

TABLE 2—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

| BLS occupation title | BLS occupation code | BLS mean hourly wage ($/hr) | Fringe benefits and support costs ($/hr) | Adjusted hourly wage ($/hr) |
|---|---|---|---|---|
| Other Technical Occupations (hereinafter, technical staff) | 29–9000 | 31.19 | 31.19 | 62.38 |

*B. Proposed Information Collection Requirements (ICRs)*

1. ICRs Regarding Global Change for Quality Assessment and Performance Improvement (Part 460)

This final rule replaces all references to ''quality assessment and performance improvement'' to read ''quality improvement'' in §§ 460.32(a)(9), 460.60(c), 460.62(a)(7), 460.70(b)(1)(iii), 460.120(f), 460.122(i), 460.130(a), 460.132(a) and (c)(3), 460.134(a), 460.136(a), (b), (c), (c)(1) and (c)(2) 460.138(b), and 460.172(c). The change also affects the heading for subpart H and the section headings for §§ 460.132, 460.134, and 460.136.

For each PO, we estimate a one-time burden of 1 hour at $62.38hr for technical staff to replace or amend existing written materials with the updated term. In aggregate, we estimate an annualized burden of 41.3 hours ([124 PO × 1 hour] ÷ 3) at a cost of $2576 (41.3 hr. × $62.38/hr). We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's 3-year approval period expires. The revised requirements and added burden have been submitted to OMB for approval under control number 0938–0790 (CMS–R–244). This information request is subject to renewal. The control number's current expiration date is June 30, 2020.

2. ICRs Regarding Application Requirements (§ 460.12)

While § 460.12 sets forth general application requirements for an entity seeking to become a PO, current regulations do not specify the process for an existing PO to submit an application to expand its service area and/or add a new PACE center site. In § 460.12(a), we proposed revisions to specify that this section also applies to expansion applications. This change would codify (in the CFR) the current PACE manual requirements pertaining to application submissions.

Until 2016 for initial PACE applications and 2017 for expansion applications, PACE applications were submitted in hard copy format. Applications were often hundreds of pages long, expensive to reproduce and transmit, and administratively inefficient. This rule finalizes our proposal to add the phrase ''in the form and manner specified by CMS'' under § 460.12(a) when describing the submission of a complete application to CMS. This change provides flexibility in the submission of applications, supporting documentation, and CMS notifications. With this change CMS expects that PACE applications will be submitted in a fully electronic submission process, thereby reducing the expense of submitting a hard copy application. CMS has successfully transitioned other programs to a fully electronic submission process, thereby facilitating a more organized and streamlined review.

Section 460.12(b) requires that a PO's application must be accompanied by an assurance (from the SAA of the state in which the program is located) indicating that the state considers the entity to be qualified as a PO and is willing to enter into a program agreement with the entity. This rule also finalizes our proposal under § 460.12(b)(2) to require that an expansion application include the state's assurance that the state is willing to amend the PACE program agreement to include new PACE center sites and/or expand its service area. This change codifies the current PACE manual provisions pertaining to the practice of application submissions.

Section 460.12(c)(1) requires that an entity submitting an application to become a PO or a PO submitting an application to expand its service area must describe the proposed service area in its application. As this is current practice, this action would not add any new burden to the applicants. To become a PO, the requirement for an entity to submit an application that describes the proposed service area is set out under § 460.22. The application for a PO to expand its service area also requires this information. The requirements and burden are currently approved by OMB under control number 0938–1326. Subject to renewal, the expiration date specific to this control number is December 31, 2021.

3. ICRs Regarding the Submission and Evaluation of Waiver Requests (§ 460.26)

Section 460.26 discusses the requirements to submit a waiver seeking to modify a PACE program requirement. Although current regulations require that a waiver request be submitted to the SAA for review prior to submitting to CMS, we finalized our proposal to reorganize the CFR text so it is clear that both current POs and applicants must submit a waiver request to the SAA prior to submitting their request to CMS. The reorganized CFR text also clarifies that a waiver request may be submitted with the application or as a separate document. The requirements for submitting a waiver request are being clarified and are not changing our currently approved burden estimates for POs and applicants. The preceding requirements and burden are approved by OMB under control number 0938–0790 (CMS–R–244, expires, June 30, 2020).

4. ICRs Regarding Notice of CMS Determination on Waiver Requests (§ 460.28)

Section 426.28(a) discusses the timeframes for CMS to make a determination and to send notification about the approval or denial of a waiver request. While current language requires that CMS approve or deny a waiver request within 90 days of receipt of the request, we revised the requirement so

that CMS must approve or deny a request after receiving a complete waiver request. Since CMS will request additional information from the PO if a waiver request is not complete, this change is needed since it is not possible to make an informed decision for approval or denial when important information is missing. This change will help facilitate CMS' ability to work with the PO or applicant to ensure that the request includes all necessary information. The change is not expected to change the burden on POs and applicants. The requirements and burden are approved by OMB under control number 0938–0790 (CMS–R–244, expires June 30, 2020).

5. ICRs Regarding the PACE Program Agreement (§ 460.32)

Sections 460.32 and 460.180(b) require that PACE program agreements specify the methodology used to calculate the Medicare capitation rate. For the Medicaid capitation rates, however, the PACE program agreement must specify the actual amount negotiated between the POs and the SAA (§§ 460.32(a)(12) and 460.182(b)). In this rule we are finalizing our proposal to amend § 460.32(a)(12) by requiring that the program agreement include the Medicaid capitation rates or the Medicaid payment rate methodology. This would be in addition to the current requirement to include the methodology used to calculate the Medicare capitation rate.

Medicaid capitation rates are developed and updated by the states (in negotiation with the POs) and approved by CMS. Operationally, states submit documentation to CMS to support their proposed PACE Medicaid capitation rates. CMS reviews the documentation to ensure the proposed rates are in compliance with the requirements of § 460.182 and provides the state with written approval of the rates. The Medicaid capitation rates are then communicated to the POs by the state in writing.

Since current regulations require that the PACE program agreement include the Medicaid capitation rates, this also requires that the PACE program agreement be updated to reflect the rates each time they change, which for most POs is annually. We do not believe it is always practical or efficient to include the actual Medicaid capitation rates in the PACE program agreement. In response, we finalized our proposal to amend § 460.32(a)(12) by requiring that the program agreement include the Medicaid capitation rates or the Medicaid payment rate methodology. We do not estimate any additional burden to the PO or the state as a result of this change. During the next regular rate update, the PACE program agreement may be revised to include the state's Medicaid payment rate methodology instead of the new rates. This would have been an update that would have already been required under the current requirements at § 460.32(a)(12). By removing the requirement that PACE program agreements be updated to include the Medicaid capitation rates, we estimate that each PO would save 30 minutes annually. Therefore, we estimate an aggregate annual reduction of 62 hours (124 POs x 0.5 hr) at a savings of $3,868 (62 hr x $62.38/hr).

The revised requirement and burden have been submitted to OMB for approval under control number 0938–0790 (CMS–R–244, expires June 30, 2020).

6. ICRs Regarding a Governing Body (§ 460.62)

Section 460.62 focuses on the ability of the PO's governing body to provide effective administration in an outcome-based environment. While § 460.62(a)(7) requires that a PO's governing body be able to administer a quality improvement program, this rule revises this section by requiring that the PO's governing body must be able to administer a quality improvement program as described in the general rule regarding quality improvement programs found in § 460.130.

Section 460.132 already requires that the PO implement a quality improvement plan and that the governing body must review the quality improvement plan on an annual basis. Revisions to § 460.62(a)(7) simply clarify what quality improvement program the PO's governing body must be able to administer. The burden associated with the aforementioned requirements is captured in § 460.132 which is approved by OMB under control number 0938–0790 (CMS–R–244, expires June 30, 2020).

7. ICRs Regarding the Creation of a Compliance Oversight Program (§ 460.63)

In the proposed rule we proposed to create a new section, § 460.63 that would have required all POs to implement compliance oversight programs for their organizations that was would parallel the existing compliance program infrastructure required of Part D plan sponsors. In particular, we proposed requiring that POs have compliance oversight programs for their entire organization with two compliance elements, 1) internal monitoring and auditing, and 2) prompt response, investigation and correction of non-compliance and fraud, waste and abuse.

As described in section III.F.3. of this final rule, we received several comments related to underestimating the burden on the proposed compliance oversight program. Specifically, commenters suggested that additional staff and resources would be required to implement the two proposed provisions across the PO's full operations. As a result of these comments we are not finalizing the proposal to require POs to adopt compliance oversight requirements related to internal monitoring and auditing but are finalizing a new § 460.63 which requires POs to have a compliance oversight program for responding to compliance issues, investigating potential compliance problems, and correcting non-compliance and fraud, waste and abuse.

In the proposed rule, based on our experience with the program we estimated 150 hours to create training materials and devote staff to implementing the new program. We estimated this burden based on our combined experience with compliance programs in MA and Part D as those programs, like PACE are structured so that there is a single organization responsible for the care of enrollees/participants. We then used that experience and modified it to account for POs size and staffing. We believe that given the size of most POs, a one-time burden of 150 hours would be a reasonable estimate on how long it would take to ensure new program materials were developed.

In this final rule, because we are not finalizing the requirement for POs to adopt internal monitoring and auditing we are reducing the 150 hour estimate of the one-time burden for each PO by a factor of 10. In addition, since we published the proposed rule, the number of POs has increased from 119 to 124.

For each PO, we estimate a one-time burden of 15 hours at $62.38/hr for technical staff to create written training materials and written procedures for the expansion of a PO's existing system of responding to and correcting non-compliance (that the PO previously established in its role as a Part D plan sponsor) to prospectively encompass all of its PACE operations. In aggregate, we estimate an annualized burden of 620 hours ([124 PO × 15 hour] ÷ 3) at a cost of $38,676 (620 hr × $62.38/hr). We are annualizing the one-time estimate since we do not anticipate any additional

burden after OMB's 3-year approval period expires.

To estimate the annual burden of reporting fraud and abuse, we assume each PO would take 20 hours annually. Therefore, the aggregate hourly burden is 2,480 hr (124 POs × 20 hours), at an aggregate cost of $154,702 (2,480 hr × $62.38/hr).

The revised requirements and added burden have been submitted to OMB for approval under control number 0938–0790 (CMS–R–244, expires June 30, 2020).

8. ICRs Regarding Personnel Qualifications for Staff With Direct Participant Contact (§ 460.64(a)(3))

Section 460.64(a)(3) requires that employees or contractors of the PO who have direct participant contact must have 1 year of experience working with a frail or elderly population. We amended this requirement by allowing the PO to hire employees or contractors with less than 1 year of experience working with a frail or elderly population as long as they meet all other qualification requirements under § 460.64(a) and receive appropriate training on working with a frail or elderly population upon hiring.

Section 460.71 already includes requirements regarding training of staff and competency evaluations for employees and contracted staff furnishing care directly to participants. In this regard the revisions to § 460.64(a)(3) do not have any effect on the burden that is currently approved by OMB under control number 0938–0790 (CMS–R–244, expires June 30, 2020).

9. ICRs Regarding Program Integrity (§ 460.68(a))

Section 460.68 was established to guard against potential conflicts of interest or certain other risks individuals and organizations could present to the integrity of the PACE program. The amendments to § 460.68(a)(3) enable POs to determine whether an individual's contact with participants would pose a potential risk because the individual has been convicted of criminal offenses related to physical, sexual, drug, or alcohol abuse or use, rather than entirely prohibiting the hiring of such individuals. To provide POs with more safeguards against potential hires that may pose a risk to participants, we also added language in § 460.68(a)(4) and (a)(5) similar to the requirements found in regulations governing Long Term Care facilities.

In § 460.68(a)(4), we finalized our proposal to add a new restriction that would prevent POs from employing or contracting 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 aide registry concerning abuse, neglect, mistreatment of residents, or misappropriation of their property. Further, in § 460.68(a)(5) we finalized our proposal to add a new restriction that would prevent POs from employing individuals or contracting with organizations or individuals who have been convicted of any of the crimes listed in section 1128(a) of the Act.

We anticipate that these changes may result in employers revising their written policies and procedures related to the hiring of individuals with criminal histories and revising their employment applications. We estimate a one-time burden of 10 hr at $62.38/hr for technical staff to make these revisions to the written policies and procedures. In aggregate, we estimate an annualized burden of 413.3 hours ([124 POs × 10 hr]/3 yr) at a cost of $25,782 (413.3 hr × $62.38/hr). We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's 3-year approval period expires. The revised requirements and added burden have been submitted to OMB for approval under control number 0938–0790 (CMS–R–244, expires June 30, 2020).

10. ICRs Regarding Marketing (§ 460.82)

Section 460.82 sets out requirements governing the marketing activities of POs. In this final rule, we are allowing the use of non-employed agents/brokers, provided they are appropriately trained, to market PACE programs. We also finalized our proposal to expand the scope of prohibited marketing practices to include additional means of marketing through unsolicited contact. In addition, we finalized our proposal to remove § 460.82(f) which requires that POs establish, implement, and maintain a documented marketing plan with measurable enrollment objectives and a system for tracking its effectiveness. We no longer believe that the documented marketing plan is necessary as we already review all marketing materials used by a PO and enrollments are already tracked by CMS. We do not believe that a marketing plan is an integral piece of the PACE program and does not provide value to the PO or to CMS. In response, we anticipate that these changes may result in POs needing to review existing policies and procedures to make sure they incorporate the changes, as well as to update any current marketing materials that may need to be changed as a result of the regulatory changes.

We estimate a one-time burden of 5 hr at $62.38/hr for technical staff to revise the written marketing policies and materials. In aggregate, we estimate an annualized burden of 206.7 hours ([124 POs × 5 hr]/3 yr) at a cost of $12,894 (206.7 hr × $62.38/hr).

At the same time, we estimate a burden reduction related to removing the requirements for the marketing plan and the tracking system. We estimate this will save each PO 10 hours annually. We estimate an aggregate reduction of 1,240 hours (124 POs × 10 hr) at a savings of $77,351 (1,240 hr × $62.38/hr).

We are annualizing the one-time estimates since we do not anticipate any additional burden after OMB's 3-year approval period expires. The revised requirements and burden have been submitted to OMB for approval under control number 0938–0790 (CMS–R–244, expires June 30, 2020).

11. ICRs Regarding the IDT (§ 460.102)

Section 460.102 currently states that primary medical care must be furnished to a participant by a PACE primary care physician. This final rule will allow primary care to be furnished by a ''primary care provider'' rather than a ''primary care physician.'' The PO must revise or develop policies and procedures for the oversight of its primary care providers.

This final rule permits a PO to have one individual fulfill two separate roles on an IDT when the individual meets applicable state licensure requirements and is qualified to fill each role and able to provide appropriate care to meet the participant's needs.

In response to public comments to proposed rule CMS–4168–P, this final rule further revises § 460.102 to delete the requirement that members of the IDT must serve primarily PACE participants.

We estimate a one-time burden of 1 hr at $62.38/hr for technical staff to update their PO's policy and procedures. In aggregate, we estimate an annualized burden of 41.3 hr ([124 POs × 1 hr]/3 yr) at a cost of $2,576 (41.3 hr × $62.38/hr). We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB' 3-year approval period expires. The revised requirements and added burden have been submitted to OMB for approval under control number 0938–0790 (CMS–R–244, expires June 30, 2020).

12. ICRs Regarding Participant Assessment (§ 460.104)

Section 460.104 sets forth the requirements for PACE participant assessments. The information obtained through the assessment is the basis for the plan of care developed by the IDT. If the IDT determines from its assessment that certain services do not need to be included in the participant's care plan, revisions to § 460.104(b) would require that the IDT must document in the care plan the reasons why such services are not needed and are not being included in the plan.

As both the development of and updates to the care plan are a typical responsibility for the IDT we believe that any burden associated with this would be incurred by persons in their normal course of business. We believe that the burden associated with the development of and updates to the care plan are exempt from the PRA in accordance with 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities and is a usual and customary business practice.

Currently, § 460.104(c) sets forth the requirements for periodic reassessments, including semiannual and annual reassessments. In this rule we are finalizing our proposal to remove the requirement in § 460.104(c)(2) requiring annual reassessments by the physical therapist, occupational therapist, dietician, and home care coordinator. In addition to the periodic reassessments, § 460.104(d) sets forth the requirements for unscheduled reassessments. In this final rule, we are revising § 460.104(d)(2) to specify that the appropriate members of the IDT may use remote technologies to conduct unscheduled reassessments when a participant or his or her caregiver or designated representative makes a request to initiate, eliminate or continue a particular service, and the IDT determines that the use of remote technology is appropriate and the service request will likely be deemed necessary to improve or maintain the participant's overall health status and the participant or his or her designated representative agrees to the use of remote technology.

While these requirements involve a collection of information, we believe that the burden associated with these requirements is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2). We believe that the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities and in the absence of federal regulation.

13. ICRs Regarding Plan of Care (§ 460.106)

Section 460.106(a) requires that a participant's plan of care be developed by the IDT promptly. This final rule amends this requirement by specifying that the IDT must develop the plan of care within 30 days of the participant's date of enrollment. In § 460.106(b), we finalized the following three new requirements pertaining to the content of the plan of care: (1) The plan must utilize the most appropriate interventions for each of the participant's care needs that advances the participant toward the measurable goals and desired outcomes; (2) the plan must identify each intervention and how it will be implemented; and (3) the plan must identify how each intervention will be evaluated to determine progress in reaching specified goals and desired outcomes.

We believe these changes provide clarification regarding the current requirements in § 460.106 on how to develop and implement a plan of care, and document any changes made to the plan of care in the participant's medical record. We expect POs to keep up-to-date with current practice standards related to plans of care and believe that most POs already implement these requirements. As we stated in the 1999 IFC (64 FR 66276), the development of the plan of care is subject to the PRA; however, we stated that the burden associated with this revision is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities and in the absence of federal regulation.

14. ICRs Regarding Explanation of Rights (§ 460.116)

Section 460.116 sets forth requirements for POs with respect to explanation of rights, such as having written policies and procedures on these rights, explaining the rights, and displaying the rights. Section 460.116(c)(1) provides that the PO must write the participant rights in English and in any other principal languages of the community. In this rule we are finalizing our proposal to require that if a state has not established a standard for making the principal language determination, a principal language of the community is any language spoken regularly at home by at least 5 percent of the individuals in the PO's service area.

We anticipate that these changes may result in technical staff revising documents. We estimate a one-time burden of 5 hr at $62.38/hr for technical staff to revise the written material about participant rights. In aggregate, we estimate an annualized burden of 206.7 hours ([124 POs × 5 hr]/3 yr) at a cost of $12,894 (206.7/hr × $62.38/hr). Section 460.116(c)(2) states that the PO must display the participant rights in a prominent place in the PACE center. In this rule we are finalizing our proposal to add the word ''PACE'' before the words ''participant rights'' to specify that participant rights specific to PACE must be displayed.

We anticipate that these changes may result in technical staff revising documents. Since the only change is the addition of the word ''PACE'' and redisplay of notices, we estimate a one-time burden of 0.5 hr at $62.38/hr for technical staff to revise the notices. In aggregate, we estimate an annualized burden of 20.7 hours ([124 POs × 0.5 hr]/3 yr) at a cost of $1,291 (20.7 hr × $62.38/hr).

We are annualizing the one-time estimates since we do not anticipate any additional burden after OMB's 3-year approval period expires. The revised requirements and added burden have been submitted to OMB for approval under control number 0938–0790 (CMS–R–244, expires June 30, 2020).

15. ICRs Regarding Quality Improvement General Rule (§ 460.130)

Section 460.130 requires a PO to develop, implement, maintain, and evaluate a quality assessment and performance improvement program which reflects the full range of their services. Section 460.140 refers to additional quality assessment activities related to reporting requirements. In this rule we are finalizing our proposal to combine § 460.140 with § 460.130 in an effort to combine all the general rules for quality improvement under the first section in subpart H, and would entirely remove § 460.140. This regulatory reorganization has no impact on any requirements or burden estimates.

16. ICRs Regarding Quality Performance Reporting (§ 460.132)

Section 460.132 sets forth requirements with respect to a Quality Assessment and Performance Improvement (QAPI) plan. In this rule we are finalizing our proposal to revise § 460.132(a) and (c)(3) by referring to a quality improvement (QI) plan. Revisions would also require that POs have a written quality improvement

plan that is collaborative and interdisciplinary in nature. Because POs are already required to have a written QAPI plan, we anticipate added burden to update the plan by making it more collaborative and interdisciplinary in nature.

We estimate a one-time burden of 1 hour at $62.38/hr to update material. In aggregate, we estimate an annualized burden of 41.3 hours ([124 POs × 1 hr]/3 yr) at a cost of $2,576 (41.3 hr × $62.38/hr) to update QI plans. We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's 3-year approval period expires. The revised requirements and added burden have been submitted to OMB for approval under control number 0938–0790 (CMS–R–244, expires June 30, 2020).

17. ICRs Regarding the Enrollment Process (§ 460.152)

Section 460.152(b)(4) states that the PO must notify CMS and the SAA if a prospective participant is denied enrollment. In this rule we are finalizing our proposal to add the phrase, ''in the form and manner specified by CMS'' and to codify current practice in which such notifications are submitted to CMS and SAA electronically, noting that this change would not revise any requirements or burden estimates. The requirements and burden are approved by OMB under control number 0938–0790 (CMS–R–244). Subject to renewal, the control number's current expiration date is June 30, 2020.

18. ICRs Regarding the Enrollment Agreement (§ 460.154)

Section 460.154 specifies the general content requirements for the enrollment agreement. Specifically, § 460.154(i) states that the enrollment agreement must provide notification that enrollment in PACE results in disenrollment from any other Medicare or Medicaid prepayment plan or optional benefit. We require additional enrollment agreement language stating that if a Medicaid-only or private pay PACE participant becomes eligible for Medicare after enrollment in PACE, he or she will be disenrolled from PACE if he or she elects to obtain Medicare coverage other than from his or her PO.

We estimate a one-time burden of 1 hour at $62.38/hr to update enrollment materials. In aggregate, we estimate an annualized burden of 41.3 hr ([124 POs × 1 hr]/3 yr) at a cost of $2,576 (41.3 hr × $62.38/hr). We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's 3-year approval period expires. The revised requirements and added burden have been submitted to OMB for approval under control number 0938–0790 (CMS–R–244). Subject to renewal, the control number's current expiration date is June 30, 2020.

19. ICRs Regarding the Enrollment Procedures (§ 460.156)

While § 460.156(a) currently requires that POs provide participants with, among other items, stickers for the participant's Medicare and Medicaid cards, we finalized our proposal to revise this requirement such that POs would no longer be required to provide participants with stickers for their Medicare and Medicaid cards. Instead, POs would be required to include the PO's phone number on the participant's PO membership card.

Since we would no longer require that POs provide stickers for participants' Medicare and Medicaid cards, we estimate an annual decrease of 1 minute for each organization. The aggregate annual reduction is 2.1 hours (124 POs × 1 minute/response) at a savings of $131 (2.1 hr × $62.38/hr). The revised requirements and burden have been submitted to OMB for approval under control number 0938–0790 (CMS–R–244). Subject to renewal, the control number's current expiration date is June 30, 2020.

Additionally, we believe that the burden associated with including the phone number of the PO on the PACE membership card is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities and is a customary business practice that would occur in the absence of federal regulation.

20. ICRs Regarding Involuntary Disenrollment (§ 460.164)

Section 460.164 specifies the conditions under which a PACE participant can be involuntarily disenrolled from a PACE program, including when a participant engages in disruptive or threatening behavior. We have approved several waivers which allow a PO to involuntarily disenroll a participant in situations where the participant's caregiver engages in disruptive or threatening behavior. In this rule we are finalizing our proposal to permit involuntary disenrollment in situations where the participant's caregiver engages in disruptive or threatening behavior, which is defined as exhibiting behavior that jeopardizes the participant's health or safety, or the safety of the caregiver or others.

The revision would obviate the need for such waivers, thereby reducing the burden on POs, states, and CMS. Since we continue to estimate that fewer than 10 POs would submit this type of waiver request each year, we believe the requirement is not subject to the PRA in accordance with 5 CFR 1320.3(c)(4).

21. ICRs Regarding the Disclosure of Review Results (§ 460.196)

Section 460.196 requires that POs make their review results available in a location that is readily accessible to their participants. In this rule we are finalizing our proposal to amend § 460.196(d) to ensure that POs make review results 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, because we believe they should be fully aware of the PO's performance and level of compliance with statutory and regulatory requirements.

We anticipate that these changes may result in technical staff redisplaying documents. We estimate a one-time burden of 0.5 hr at $62.38/hr for technical staff to redisplay the review results. In aggregate, we estimate an annualized burden of 20.7 hours ([124 POs × 0.5 hr]/3 yr) at a cost of $1,291 (20.7 hr × $62.38/hr). We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB' 3-year approval period expires. The revised requirements and added burden have been submitted to OMB for approval under control number 0938–0790 (CMS–R–244, expires June 30, 2020).

22. ICRs Regarding the Maintenance of Records and Reporting of Data (§ 460.200)

In accordance with § 460.200(f)(1), POs must retain records for the longest of the following periods: the period of time specified in state law; 6 years from the last entry date; or for medical records of disenrolled participants, 6 years after the date of disenrollment. In this rule we are finalizing our proposal to change this requirement from 6 to 10 years.

We believe that the burden to store records for 6 years is sufficient to cover the storage for 4 more years, especially as data are increasingly likely to be stored electronically. As for the storage of electronic records, a server is not needed since a terabyte hard drive costs under $200 and can store a terabyte of data securely. Furthermore, most servers have additional capacity which could be used before more expenses are needed.

Thus, the expense to go from 6 years to 10 years is minimal so we are not itemizing this burden. The requirements and burden for storing records for 6 years are currently approved by OMB under control number 0938–0790 (CMS–R–244, expires June 30, 2020). The revised requirements have been submitted to OMB under this control number for approval.

*C. Summary of Annual Burden Estimates for Requirements*

TABLE 3—INFORMATION COLLECTION REQUIREMENTS AND BURDEN *

| Section(s) in title 42 of the CFR | OMB control number (expires June 30, 2020) | Respondents | Responses (per respondent) | Burden per response (hr) | Total time (hr) | Labor cost per hour ($/hr) | Total cost (annual in dollars) |
|---|---|---|---|---|---|---|---|
| part 460 (global term change) | 0938–0790 | 124 | 1 | 1 | **41.3 | 62.38 | **2,578 |
| § 460.32 (program agreement) | 0938–0790 | 124 | 1 | -0.5 | −62 | 62.38 | −3,868 |
| § 460.63 (update policies and procedures) | 0938–0790 | 124 | 1 | 15 | 620.0 | 62.38 | 38,676 |
| § 460.63 (annual report of fraud and abuse) | 0938–0790 | 124 | 1 | 20 | 2,480.0 | 62.38 | 154,702 |
| § 460.68(a) (program integrity for PACE) | 0938–0790 | 124 | 1 | 10 | 413.3 | 62.38 | 25,784 |
| § 460.82 (revise policies and written materials) | 0938–0790 | 124 | 1 | 5 | 206.7 | 62.38 | 12,892 |
| § 460.82 (remove requirements) | 0938–0790 | 124 | 1 | −10 | −1240 | 62.38 | −77,351 |
| § 460.102 (update policies and procedures) | 0938–0790 | 124 | 1 | 1 | 41.3 | 62.38 | 2,578 |
| § 460.116 (revise explanations of rights) | 0938–0790 | 124 | 1 | 5 | 206.7 | 62.38 | 12,892 |
| § 460.116 (redisplay 'participant rights' as 'PACE participant rights') | 0938–0790 | 124 | 1 | 0.5 | 20.7 | 62.38 | 1,289 |
| § 460.132 (update QI plan) | 0938–0790 | 124 | 1 | 1 | 41.3 | 62.38 | 2,578 |
| § 460.154 (revise enrollment agreement) | 0938–0790 | 124 | 1 | 1 | 41.3 | 62.38 | 2,578 |
| § 460.156 (removing sticker requirement) | 0938–0790 | 124 | 1 | −0.017 | −2.1 | 62.38 | −131 |
| § 460.196 (disclosure of review results) | 0938–0790 | 124 | 1 | 0.5 | 20.7 | 62.38 | 1,289 |
| TOTAL | | 124 | 1 | varies | 2,829.2 | Varies | 176,486 |

* The $154,702 burden for § 460.63 is an annual burden. All other cost burdens are first year burdens which have been annualized by dividing by 3 since we do not anticipate any further burden. All items with savings are annual for each of the 3 years.

** To clarify rounding procedures: 2,578 = 124 total respondents × ⅓ (annualized for 3 years) × 62.38. However, the 124/3 is displayed as 41.3 not 41.3333.

*D. Submission of PRA-Related Comments*

We have submitted a copy of this final rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by OMB.

We invite public comments on these information collection requirements. If you wish to comment, please identify the rule (CMS–4168–F) the ICR's CFR citation, CMS ID number, and OMB control number. Comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, *Fax:* (202) 395–5806 *OR, Email: OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the collection(s) summarized in this rule, you may make your request using one of following:

1. Access CMS' website at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

PRA-related comments are due July 3, 2019.

## VI. Regulatory Impact Statement

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year).

To analyze the impact of this rule we reviewed its 45 provisions. We determined that 20 of the provisions have no cost or savings so we are not discussing them in this statement. Twenty two other provisions are scored in the information collection requirements section with aggregate annualized burden (for the first 3 years) of $176,486 ($257,836 in costs minus $81,350 in savings). One of those 22 provisions, (the compliance oversight provision), has effects outside of the scope of the PRA, so the additional impacts of it, and the remaining three provisions are assessed in this regulatory impact statement.

The provision discussed in section III.K.1. of this final rule, the modification of § 460.182 regarding Medicaid payment, has no savings or cost; the provision discussed in section III.L.1. of this final rule, the modification of § 460.190 regarding monitoring, has a savings of $1,523,253 to POs and a savings of $2,638,144 to the government without any transfer to POs; the provision discussed at III.G.4. of this final rule, the modification of § 460.104(d)(2) to allow use of remote technologies for certain participant assessments has a qualitative savings which is not further quantified. It follows that this final rule has a net savings of 4 million arising primarily from the monitoring provision. These estimates are summarized in detail in Table 4. We discuss these four provisions in more detail below.

TABLE 4—IMPACT [1] [2] OF FINAL RULE BY PROVISION AND YEAR

| Provision name | Regulatory citation | Section of final rule | 1st year savings | 2nd and later year savings |
|---|---|---|---|---|
| Medicaid Payment | § 460.182 | III.K.1 | $0 | $0 |
| Monitoring | § 460.190 | III.L.1 | [3] 4,161,397 | [3] 4,161,397 |
| Participant Assessment | § 460.104(d)(2) | III.G.4 | 0 | 0 |
| Various [4] | Various | V | (382,754) | (73,352) |
| Total | | | 3,778,643 | 4,088,045 |

**Notes:**
[1] Positive numbers indicate savings; negative numbers indicate cost.
[2] Although the Participant Assessment provision (Section III.G.4, § 460.104(d)(2)) is not scored quantitatively, it is a savings. The Medicaid provision is neither a savings nor cost. The additional flexibility for the IDT provision has neither cost nor savings to the government due to the fact that most POs are currently exercising these flexibilities through PACE waivers.
[3] The government saves $2,638,144 and the POs save $1,523,253.
[4] The numbers in this row are derived from the summary Table 3 in the Collection of Information section as follows: The first year cost is 382,754 and is the sum of three items: (i) The aggregate of all items saved is $81,350, (ii) The annual cost of reporting fraud and abuse is $154,702, (iii) the aggregate of all items with cost minus the $154,702 when multiplied by 3 is 309,402 (the numbers in Table 3 are divided by 3 to create an annualized cost and hence have to be multiplied by 3). The 2nd and later year costs are $73,352, the difference of $81,350 (the aggregate of all items with savings) and the $154,702 annual cost of reporting fraud and abuse.

*A. Medicaid Payment (§ 460.182 (Discussed in Section III.K.1. of This Final Rule))*

The provision aims to ensure that the Medicaid rate paid under the PACE program agreement is not only less than what would otherwise have been paid outside of PACE for a comparable population, but is also sufficient for the population served under the PACE program, which we believed 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. We will continue to review and approve Medicaid capitation rates under PACE. Therefore, we do not believe this provision will affect spending.

*B. Participant Assessment (§ 460.104(d) Discussed in Section III.G.4 of This Final Rule)*

This provision reduces the required IDT members at a ''change in participant status'' reassessment under § 460.104(d)(1) from 8 to 3 members and allows use of remote technology to conduct reassessments for certain participant service requests under § 460.104(d)(2). We expect the reduction of required IDT members from eight to three will result in savings by reducing labor costs. Similarly, we expect the use of remote technology for reassessments related to service delivery requests will result in savings from reduced travel costs for PO staff and PACE participants.

We are scoring this as a qualitative savings and not further quantifying it. The primary reasons for not quantifying it further are due to our inability to assess the number of these participant service requests and the typical travel time that would have been required for such reassessments. Furthermore, removing a travel requirement for requests might result in an increase in requests and this effect is difficult to quantify.

*C. Monitoring (§ 460.190 (Discussed in Section III.L.1. of This Final Rule))*

This provision would result in savings to both the POs and the government without any transfers to the POs. We estimate separately the savings for POs and the government below.

To estimate the savings from the monitoring provision we use the following assumptions, based on our experience with audits. Since publishing the proposed rule, we have implemented a new PACE audit protocol. Having used that new protocol for two years, we now have a better understanding of the costs of audits to both PO's and the government. We are updating our analysis to reflect our current projections, which result in significantly increased estimated savings for both POs and the government.

Under the provision we are finalizing, we estimate that we will perform 35 audits per year, 20 during PO trial periods and 15 post trial period (routine) audits. If we did not finalize this provision, we estimate that we would perform 72 audits per year, 34 during PO trial periods, and 38 post trial period (routine) audits.

In the proposed rule, we made the following assumptions in estimating costs of an audit for a PO. Mean hourly wages have been updated to reflect current estimates. The assumptions are summarized in Table 5.

- *Personnel:* We estimated:

++ 2 Medical and Health Service Managers, occupational code 11–9111 on the Bureau of Labor Statistics (BLS) website accessible at *www.bls.gov/oes/current/oes_nat.htm,* with an average hourly wage of $53.69

++ 1 Secretary and Administrative assistant, code 43–6010, with an average hourly wage of $19.74.

However, in the time since the proposed rule was published, CMS has implemented and operated a new PACE audit protocol which has allowed us to better estimate the costs of audits on a PO. We now estimate the following for personnel:

TABLE 5—NATIONAL OCCUPATIONAL MEAN HOURLY WAGE AND ADJUSTED HOURLY WAGE

| Occupation title | Occupation code | Mean hourly wage ($/hr) |
|---|---|---|
| Nurse Manager | 11–9111 | 53.69 |
| Executive Assistant | 43–6011 | 28.56 |
| Medical Records and Health Information Technician | 29–2071 | 20.59 |
| Compliance Officer | 13–1041 | 34.39 |

Additionally, in the proposed rule we estimated 80 hours uniformly per person; 40 hours the week before the audit and 40 hours the week of the audit. Based on updated information, we now estimate that audits will take approximately 150 hours per person for POs to complete. This estimate includes all of the pre-audit work, including (i) compiling and (ii) submitting audit documentation; (iii) 2 weeks of audit fieldwork; the post-audit work of (iv) collecting and (v) submitting impact analyses, (vi) reviewing and (vii) commenting on the draft audit report, and (viii) submitting and (ix) implementing corrective action plans for conditions of non-compliance.

• *Fringe benefits:* We estimate 100 percent (of hourly wage) for fringe benefits and overhead.

Based on these assumptions, we can compute the difference between 72 and 35 audits per year. In the proposed rule, we estimated that POs would save approximately $737,336.00. However, based on the new assumptions, and as a result of more accurate estimates, we now estimate that savings per year to POs would be $1,523,253. The calculations are exhibited in Table 6.

TABLE 6—PO SAVINGS FROM FINALIZING THE MONITORING PROVISION

| Occupational title | Code | Wage/hr | Fringe benefit factor | Number staff required | Hours per audit | Number of audits per year if provision is not finalized | Number of audits per year if provision finalized |
|---|---|---|---|---|---|---|---|
| Nurse Manager | 11–9111 | $53.69 | 2 | 1 | 150 | 72 | 35 |
| Executive Assistant | 43–6011 | 28.56 | 2 | 1 | 150 | 72 | 35 |
| Medical Records and Health Information Technician | 29–2071 | 20.59 | 2 | 1 | 150 | 72 | 35 |
| Compliance Officer | 13–1041 | 34.39 | 2 | 1 | 150 | 72 | 35 |
| Summary descriptions | | | | | Cost per audit | Aggregate cost if not finalized | Aggregated cost if finalized |
| Summary dollar amounts | ..... | ..... | ..... | ..... | $41,169 | $2,964,168 | $1,440,915 |
| Savings (Not finalized minus finalized) | ..... | ..... | ..... | ..... | ..... | ..... | 1,523,253 |

In the proposed rule we used the following assumptions to estimate the cost of an audit for CMS.

• 2.5 FTE (Between 2 and 3 per audit). This number is based on CMS experience across different geographic regions some of which use 2 FTE and some of which use 3 FTE.

• *Hours spent:*

++ 220 hours at the GS–13 level with an hourly average wage of $46.46

++ 40 hours at the GS–15 level with an hourly average wage of $64.59

Based on our experiences auditing POs since publishing this proposed rule, we are now using the revised assumptions:

• 3 FTEs to conduct each audit and 1 FTE for audit oversight and 1 FTE to conduct audit close out activities.

• *Hours spent:*

++ 220 hours at the GS–13 level with an hourly average wage of $46.46 (includes 3 FTEs for 200 hours each and 1 FTE for 20 hours)

++ 60 hours at the GS–15 level with an hourly average wage of $64.59

In the proposed rule, we estimated that travel cost approximately $1,395 per audit. However, since this proposed rule was published, we now estimate that travel costs approximately $5,940 per audit.

Finally, we continue to have the following additional assumptions related to government costs.

• *Fringe Benefits:* We estimate 100 percent (of hourly wage) for fringe benefits

Based on these assumptions, we can compute the difference between 72 and 35 audits per year. In the proposed rule, we estimated that the savings to CMS was $1,029,454.70 per year. Based on the revised assumptions, we now estimate the savings to the government to be $2,638,144. The calculations are exhibited in Table 7.

TABLE 7—GOVERNMENT SAVINGS FROM FINALIZING THE MONITORING PROVISION

| Occupational title | Code | Mean hourly wage | Fringe benefit | Number staff needed | Hours per audit | Number of audits per year if provision is not finalized | Number of audits per year if provision finalized |
|---|---|---|---|---|---|---|---|
| CMS Staff Employee | GS 13–1 | $46.46 | 2 | 3 | 200 | 72 | 35 |
| CMS Staff Employee | GS 13–1 | 46.46 | 2 | 1 | 20 | 72 | 35 |
| CMS Manager | GS 15–1 | 64.59 | 2 | 1 | 60 | 72 | 35 |
| Cost of Travel | ..... | 1,980.00 | 1 | 3 | 1 | 72 | 35 |
| Summary descriptions | | | | | Cost per audit | Aggregate cost if not finalized | Aggregated cost if finalized |
| Summary dollar amounts | ..... | ..... | ..... | ..... | $71,301 | $5,133,686 | $2,495,542 |
| Savings (Not finalized minus finalized) | ..... | ..... | ..... | ..... | ..... | ..... | 2,638,144 |

*D. The Compliance Oversight Program (§ 460.63 (Discussed in Section III.F.3. of This Proposed Rule))*

In the proposed rule, we pointed out that current regulations do not require POs to implement compliance programs similar to those required in the regulations governing the MA and Part D programs, and we proposed to adopt certain compliance oversight requirements through the addition of § 460.63.

Currently, POs participating in the Part D program are required to have a compliance plan with measures that prevent, detect, and correct fraud, waste and abuse as specified in § 423.504(b)(4)(vi) governing the Part D program. We proposed adopting PACE program requirements that would result in POs expanding their already existing Part D compliance programs under the Part D program to ensure compliance oversight for the totality of the PO's operations. Specifically, we proposed to require all POs to establish and implement compliance efforts geared toward: (1) Routine monitoring and identification of compliance risks and (2) 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 ensuring ongoing compliance with CMS requirements.

In the proposed rule, we proposed a burden associated with the requirements under § 460.63 which would be the time and effort for each of the 119 POs to develop, adopt, and implement procedures for conducting internal auditing and monitoring to ensure compliance with CMS program requirements. POs would also be required to develop measures to detect, correct, and prevent fraud, waste, and abuse. POs will be required to devote technical staff to developing and implementing these procedures.

In the proposed rule, we estimated a one-time burden of 150 hours at $59.44 per hour for technical staff to develop the aforementioned procedures and measures at an annualized cost of $353,668 (119 POs × 59.44/hour × 150/3) for each of the first 3 years. We estimated this burden based on our combined experience with compliance programs in MA and Part D. Since we proposed to utilize two of the same compliance requirements in PACE as are used in MA and Part D, we believe this comparison will be accurate. We then used that experience and modified it to account for POs size and staffing. We believe that given the size of most POs, a one-time burden of 150 hours would be a reasonable estimate on how long it would take to ensure new program materials and measures were developed.

Additionally, once the program has been developed and is running, we indicated in our proposal that the PO would have to spend some time going forward monitoring their own compliance, and reporting and responding to any suspected fraud, waste and abuse. Therefore, in the proposed rule, we estimated a burden of 200 hours at $59.44 per hour for technical staff to complete these activities including, when warranted, revision of the aforementioned program materials and monitoring measures. Our estimate also included the routine monitoring and identification of compliance risks as identified in the course of self-evaluations and audits. We estimated total aggregate annual cost at $1,414,672 (119 organizations × 200 hour × $59.44 per hour). Again, given the size of POs and the limited number of participants, we believed the burden to be small, and we believed that 200 hours would cover the ongoing responsibilities of each PO. This includes PO monitoring of its own compliance; corrective action as a result of that monitoring; and updating PO monitoring measures and procedures.

We solicited comments from POs regarding this burden estimate in the proposed rule. The following is a summary of the public comments we received on the ''Compliance Oversight Program'' proposed burden estimate and our response to those comments.

*Comment:* Many commenters suggested that we underestimated the burden of implementing a compliance oversight program in PACE. These commenters suggested more staff would be needed, and the cost and hours to both implement and maintain a compliance oversight program were underestimated. One commenter suggested we use our burden estimates for the monitoring proposal in Subpart K in order to estimate the burden of POs implementing an internal monitoring and auditing program as a part of the compliance oversight program, since the same staff would likely be used. One commenter mentioned that the time involved in conducting ongoing internal monitoring would be similar to the time POs currently spend when undergoing a CMS audit. Another commenter mentioned that there would be a large increase in manual data collection which needed to be included in the burden.

*Response:* Based on comments received, and because we have a strong policy interest in not creating undue burden, we have reviewed our proposed provision and the proposed burden associated with it. We believe that the majority of the burden associated with our initial proposal is due to the first element of our proposal which would have required POs to adopt internal monitoring and auditing that would cover all PACE operations. Because POs are currently required to have a compliance program as Part D plan sponsors, we estimated the cost of new PACE requirements would be to update materials and expand efforts currently in place under Part D to implement these new PACE provisions and ensure that the full PACE operations were being affirmatively reviewed and that compliance concerns identified anywhere in the PO's operation were being promptly addressed. Although we did not separately analyze the cost of each of these two elements in our first proposal, the majority of burden was associated with the development and implementation of the internal monitoring and auditing element. We are not finalizing that element at this time in order to further evaluate the anticipated burden. We are finalizing the compliance oversight requirements which require promptly responding to non-compliance and fraud, waste and abuse. Because we are not expanding the scope of what an organization is required to monitor and because we believe POs are currently addressing compliance concerns in their organizations as they arise outside of Part D, we anticipate only a minimal burden with this element. Therefore, we revised our burden estimates and decreased the hours to implement this revised provision by a factor of 10. The number of hours would therefore be reduced from 150 hours to 15 hours for one staff member. Additionally, we decreased the estimate of how many hours an organization will spend following the implementation of this provision from 200 to 20 hours. We decreased these numbers because we are not finalizing the element that would have required POs to expand their internal monitoring and auditing efforts, and we are only finalizing the provision that would require an organization to have a system for responding to, investigating and correcting non-compliance. Since there will be no increased data collection, we believe this reduced burden accurately reflects the revised provision.

As discussed above, and as a result of these comments, we have decided not to

finalize the first proposed element related to internal monitoring and auditing, and finalize only the second element of the proposed compliance oversight program, related to responding to, correcting and reporting non-compliance and fraud, waste and abuse.

As in the proposed rule we make separate estimates for the initial year and for subsequent years. Additionally, since the proposed rule was published the number of POs increased from 119 to 124. Because we are not adopting the element of the proposal that would have required POs to establish internal monitoring and auditing the estimates of 150 and 200 hours use in the proposed rule are reduced by a factor of 10. Table 8 exhibits the estimates under the proposed and final rule. As we are finalizing, we estimate an initial year burden of $116,026.80 (or $38,675.6 per year for 3 years) and a subsequent burden of $154,702.40 for later years.

TABLE 8—IMPACT OF THE COMPLIANCE PROVISION (PROPOSED AND FINAL RULE)

| Item | Proposed rule initial year | Final rule initial year | Proposed rule subsequent years | Final rule subsequent years |
|---|---|---|---|---|
| Number of POs | 119 | 124 | 119 | 124 |
| Wage estimates per hour | 59.44 | 62.38 | 59.44 | 62.38 |
| Hours needed to develop and implement training | 150 | 15 | 200 | 20 |
| Total burden [1] | $1,061,004 | $116,027 | $1,414,672 | $154,702 |

**Notes:**
[1] Total burden is the product of the previous three rows: Number of POs * Wages Estimates Per Hour * Hours needed to develop and implement training.

Based on the above analysis, we have determined that this final rule does not reach the economic threshold, and therefore, it is neither an ''economically significant rule'' under E.O. 12866, nor a ''major rule'' under the Congressional Review Act.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has significant impact on a substantial number of entities. However, as shown in Table 4, this final rule has a net impact of savings, not cost, and consequently, we are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that our changes to this regulation would not have a significant economic impact, nor net additional costs requiring possible regulatory relief, on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. As previously explained, this rule will allow for increased staffing flexibility among POs; therefore, we are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this final rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately $154 million This rule will not mandate any requirements for state, local, or tribal governments nor would it result in expenditures by the private sector meeting that threshold in any 1 year.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Under Executive Order 13132, this final rule will not significantly affect the states beyond what is required and provided for under sections 1894 and 1934 of the Act. It follows the intent and letter of the law and does not usurp state authority beyond what the Act requires. This rule describes the processes that must be undertaken by CMS, the states, and POs in order to implement and administer the PACE program.

As noted previously, sections 1894 and 1934 of the Act describe a cooperative relationship between the Secretary and the states in the development, implementation, and administration of the PACE program. The following are some examples of areas in which we collaborated with states to establish policy and procedures for PACE, with references to the relevant sections of the Act:

(1) Establishing procedures for entering into, extending, and terminating PACE program agreements—sections 1894(e)(1)(A) and 1934(e)(1)(A) of the Act;

(2) Establishing procedures for excluding service areas already covered under other PACE program agreements in order to avoid unnecessary duplication of services and impairing the financial and service viability of existing programs—sections 1894(e)(2)(B) and 1934(e)(2)(B) of the Act;

(3) Establishing procedures for POs to make available PACE program data—sections 1894(e)(3)(A)(i)(III) and 1934(e)(2)(A)(i)(III) of the Act;

(4) In conjunction with the PO, developing and implementing health status and quality of life outcome measures for PACE participants—sections 1894(e)(3)(B) and 1934 (e)(3)(B) of the Act;

(5) Conducting comprehensive annual reviews of POs during the trial period—sections 1894(e)(4)(A) and 1934(e)(4)(A) of the Act;

(6) Establishing the frequency of ongoing monitoring—sections 1894(e)(4)(B) and 1934(e)(4)(B) of the Act;

(7) Establishing a mechanism for exercising enforcement authority—sections 1894(e)(6)(A) and 1934(e)(6)(A) of the Act.

For this reason, prior to publishing the 2006 final rule, we obtained state input in the early stages of policy development through conference calls with state Medicaid agency representatives. The statute requires that states designate the agency of the state responsible for the administration of the

PACE program. Although the state may designate the state Medicaid agency to administer the PACE program, another agency may be named. The eight agencies that volunteered to participate in these discussions represented a balanced view of states; some with PACE demonstration site experience and some who were not yet involved with PACE, but were interested in providing input to establish a new long term care optional benefit. The calls were very productive in understanding the variety of state concerns inherent in implementing a new program. In addition, in order to formulate processes to operationalize the PACE program, we have maintained ties with state representatives through monthly conference calls to obtain information on a variety of topics including the applications review and approval process, data collection needs, and enrollment/disenrollment issues. We are committed to continuing this dialogue with states to ensure this cooperative atmosphere continues as we administer the PACE program.

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 and requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' OMB's interim guidance, issued on April 5, 2017, *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/M-17-21-OMB.pdf,* explains that ''E.O. 13771 deregulatory actions are not limited to those defined as significant under E.O. 12866 or OMB's Final Bulletin on Good Guidance Practices.'' Accordingly, this final rule is considered an E.O. 13771 deregulatory action. We estimate that this rule generates $3.3 million in annualized cost savings, discounted at 7 percent relative to year 2016, over a perpetual time horizon.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

**List of Subjects**

*42 CFR Part 423*

Administrative practice and procedure, Emergency medical services, Health facilities. Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

*42 CFR Part 460*

Aged, Health care, Health records, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

## PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 1. The authority citation for part 423 is revised to read as follows:

**Authority:** 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

**§ 423.4 [Amended]**

■ 2. Section 423.4 is amended in paragraph (4) of the definition of ''Service area (Service area does not include facilities in which individuals are incarcerated.)'' by removing the reference ''§ 460.22 of this chapter'' and adding in its place the reference ''§ 460.12(c) of this chapter''.

## PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 3. The authority citation for part 460 is revised to read as follows:

**Authority:** 42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f).

■ 4. Section 460.3 is added to read as follows:

**§ 460.3 Part D program requirements.**

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

■ 5. Section 460.10 is revised to read as follows:

**§ 460.10 Purpose.**

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

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

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

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

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

■ 6. Section 460.12 is revised to read as follows:

**§ 460.12 Application requirements.**

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

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

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

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

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

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

■ 7. Section 460.18 is amended by—

■ a. Revising the introductory text;

■ b. Revising paragraph (b); and

■ c. Removing paragraph (c).

The revisions read as follows:

**§ 460.18 CMS evaluation of applications.**

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

* * * * *

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

■ 8. Section 460.20 is amended by—

■ a. Revising paragraph (a) introductory text;

■ b. Removing paragraph (a)(3);

■ c. Redesignating paragraphs (b) through (d) as paragraphs (c) through (e);

■ d. Adding a new paragraph (b); and

■ e. Revising newly redesignated paragraphs (c) through (e).

The revisions and addition read as follows:

**§ 460.20 Notice of CMS determination.**

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

* * * * *

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

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

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

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

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

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

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

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

**§ 460.22 [Removed]**

■ 9. Section 460.22 is removed.

■ 10. Section 460.26 is amended by revising paragraphs (a) and (b) introductory text to read as follows:

**§ 460.26 Submission and evaluation of waiver requests.**

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

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

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

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

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

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

* * * * *

■ 11. Section 460.28 is revised to read as follows:

**§ 460.28 Notice of CMS determination on waiver requests.**

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

(1) Approves the waiver request.

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

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

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

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

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

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

■ 12. Section 460.32 is amended by revising paragraphs (a)(9) and (12) to read as follows:

**§ 460.32 Content and terms of PACE program agreement.**

(a) * * *

(9) A description of the organization's quality improvement program.

* * * * *

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

* * * * *

■ 13. Section 460.40 amended by—

■ a. Redesignating the introductory text and paragraphs (a) through (e), (f) introductory text, (f)(1) and (2), and (g) through (j) as paragraphs (a) introductory text and (a)(1) through (5), (6) introductory text, (6)(i) and (ii), and (7) through (10) respectively; and

■ b. Adding new paragraph (b).

The addition reads as follows:

**§ 460.40 Violations for which CMS may impose sanctions.**

* * * * *

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

■ 14. Section 460.46 is amended—

■ a. By revising paragraph (a) introductory text.

■ b. In paragraph (a)(1) by removing the reference ''§ 460.40(c) or (d)'' and adding in its place the reference ''§ 460.40(a)(3) or (4)'';

■ c. In paragraph (a)(2) by removing the reference ''§ 460.40(e)'' and adding in its place the reference ''§ 460.40(a)(5)''; and

■ d. In paragraph (a)(3) by removing the reference ''§ 460.40(f)(1)'' and adding in

its place the reference ''§ 460.40(a)(6)(i)''.

The revision reads as follows:

**§ 460.46 Civil money penalties.**

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

* * * * *

■ 15. Section 460.60 is amended by—
■ a. Removing paragraph (a);
■ b. Redesignating paragraphs (b), (c) and (d) as paragraphs (a), (b), and (c);
■ c. Revising newly redesignated paragraphs (b) and (c)(3);
■ d. Adding new paragraph (d).

The revisions and addition read as follows:

**§ 460.60 PACE organizational structure.**

* * * * *

(b) *Medical director.* The organization must employ, or contract with in accordance with § 460.70, a medical director who is responsible for the delivery of participant care, for clinical outcomes, and for the implementation, as well as oversight, of the quality improvement program.

(c) * * *

(3) Except as provided in paragraph (d) of this section, a PACE organization planning a change in organizational structure must notify CMS and the State administering agency, in writing, at least 14 days before the change takes effect.

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

■ 16. Section 460.62 is amended by revising paragraph (a)(7) to read as follows:

**§ 460.62 Governing body.**

(a) * * *

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

* * * * *

■ 17. Section 460.63 is added to read as follows:

**§ 460.63 Compliance oversight requirements.**

A PACE organization must adopt and implement effective compliance oversight requirements, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements, as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance oversight program must, at a minimum, include establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with CMS requirements.

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

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

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

■ 18. Section 460.64 is amended by revising paragraphs (a) introductory text, (a)(3), and (4) to read as follows:

**§ 460.64 Personnel qualifications for staff with direct participant contact.**

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

* * * * *

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

(4) Meet a standardized set of competencies for the specific position description established by the PACE organization before working independently.

* * * * *

**§ 460.66 [Amended]**

■ 19. Section 460.66 is amended by removing paragraphs (b) and (c) and removing the paragraph designation from paragraph (a).

■ 20. Section 460.68 is amended—
■ a. In paragraph (a)(2) by removing the word ''or'' after '';'';
■ b. By revising paragraph (a)(3); and
■ c. Adding paragraphs (a)(4) and (5).

The revision and additions read as follows:

**§ 460.68 Program integrity.**

(a) * * *

(3) If the PACE organization determines that an individual's contact with participants would pose a potential risk because the individual has been convicted of one or more criminal offenses related to physical, sexual, drug, or alcohol abuse or use;

(4) Who have been found guilty of abusing, neglecting, or mistreating individuals by a court of law or who have had a finding entered into the State nurse aide registry concerning abuse, neglect, mistreatment of residents, or misappropriation of their property; or

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

* * * * *

■ 21. Section 460.70 is amended—
■ a. By revising paragraph (b)(1)(iii);
■ b. By redesignating paragraphs (d)(5)(vi) through (ix) as paragraphs (d)(6)(i) through (iv);
■ c. By adding paragraph (d)(6) introductory text;
■ d. By revising newly redesignated paragraphs (d)(6)(i), (ii) and (iii);
■ e. In paragraph (e), by removing the term ''PACE Center services'' and adding in its place the term ''PACE center services'' wherever it appears; and
■ f. In paragraph (e)(2) by removing the reference ''§ 460.98(d)'' and adding in its place the reference ''§ 460.98(c)''.

The revisions and addition read as follows:

**§ 460.70 Contracted services.**

* * * * *

(b) * * *

(1) * * *

(iii) A contractor must comply with the requirements of this part with respect to service delivery, participant rights, and quality improvement activities.

* * * * *

(d) * * *

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

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

(ii) Participate in interdisciplinary team meetings as required.

(iii) Be accountable to the PACE organization.

* * * * *

■ 22. Section 460.71 is amended by revising paragraphs (a)(1) and (b)(4), and adding paragraphs (c) and (d) to read as follows:

**§ 460.71 Oversight of direct participant care.**

(a) * * *

(1) The PACE organization must provide each employee and all contracted staff with an orientation that includes, at a minimum, the organization's mission, philosophy, policies on participant rights, emergency plan, ethics, the PACE benefit, and any policies related to the job duties of specific staff.

* * * * *

(b) * * *

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

* * * * *

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

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

■ 23. Section 460.82 is amended by revising paragraphs (c)(1), (e) introductory text, (e)(3), (e)(4), (e)(5) and removing paragraph (f) to read as follows:

**§ 460.82 Marketing.**

* * * * *

(c) * * *

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

* * * * *

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

* * * * *

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

(4) Marketing by any individual or entity that is directly or indirectly compensated by the PACE organization based on activities or outcomes unless the individual or entity has been appropriately trained on PACE program requirements, including but not limited to, subparts G and I of this part.

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

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

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

■ 24. Section 460.98 is amended—

■ a. By revising paragraphs (c)(1);

■ b. In paragraph (d) heading by removing the term ''Pace Center'' and adding in its place the term ''PACE center''; and

■ c. In paragraph (d)(3) by removing the term ''Pace center'' and adding in its place the term ''PACE center''.

The revision reads as follows:

**§ 460.98 Service delivery.**

* * * * *

(c) * * *

(1) Primary care, including services furnished by a primary care provider as defined in § 460.102(c) and nursing services.

* * * * *

**§ 460.100 [Amended]**

■ 25. Section 460.100 is amended in paragraph (e)(3)(i) by removing the term ''POs'' and adding in its place the term ''PACE organizations,'' and by removing the term ''PO'' and adding in its place the term ''PACE organization''.

■ 26. Section 460.102 is amended by—

■ a. Revising paragraphs (a)(1), (b) introductory text, (b)(1), (c) introductory text, (c)(1), and (c)(2) introductory text;

■ b. Removing paragraph (d)(3);

■ c. Redesignating paragraph (e) as paragraph (f); and

■ d. Adding paragraph (e).

The revisions and additions read as follows:

**§ 460.102 Interdisciplinary team.**

(a) * * *

(1) Establish an interdisciplinary team, composed of members that fill the roles described in paragraph (b) of this section, at each PACE center to comprehensively assess and meet the individual needs of each participant.

* * * * *

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

(1) Primary care provider.

* * * * *

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

(i) A primary care physician.

(ii) A community-based physician.

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

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

(2) Each primary care provider is responsible for the following:

* * * * *

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

* * * * *

■ 27. Section 460.104 is amended by—

■ a. Revising paragraphs (a)(1), (a)(2) introductory text, (a)(2)(i), (3), (4) introductory text, (b), (c), (d) introductory text, (d)(1) and (d)(2) introductory text;

■ b. Redesignating paragraphs (d)(2)(i) through (v) as paragraphs (d)(2)(ii) through (vi);

■ c. Adding new paragraph (d)(2)(i).

The revisions and additions read as follows:

**§ 460.104 Participant assessment.**

(a) * * *

(1) *Basic requirement.* The interdisciplinary team must conduct an initial in-person comprehensive assessment on each participant. The assessment must be completed in a

timely manner in order to meet the requirements in paragraph (b) of this section.

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

(i) Primary care provider

* * * * *

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

(4) *Initial comprehensive assessment criteria.* The initial in-person comprehensive assessment must at a minimum include the evaluation of:

* * * * *

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

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

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

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

(1) Primary care provider.

(2) Registered nurse.

(3) Master's-level social worker.

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

(d) *Unscheduled reassessments.* In addition to semi-annual reassessments, unscheduled reassessments may be required based on the following:

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

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

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

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

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

* * * * *

■ 28. Section 460.106 is amended by revising paragraph (a) and by adding paragraphs (b)(3), (4), and (5) to read as follows:

**§ 460.106 Plan of care.**

(a) *Basic requirement.* Within 30 days of the date of enrollment, the interdisciplinary team members specified in § 460.104(a)(2) must develop a comprehensive plan of care for each participant based on the initial comprehensive assessment findings.

(b) * * *

(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.

* * * * *

■ 29. Section 460.112 is amended by—

■ a. Revising paragraph (b)(1)(i);

■ b. Removing paragraph (b)(1)(ii);

■ c. Redesignating paragraph (b)(1)(iii) as paragraph (b)(1)(ii); and

■ d. Revising paragraphs (b)(3) and (c)(3).

The revisions read as follows:

**§ 460.112 Specific rights to which a participant is entitled.**

* * * * *

(b) * * *

(1) * * *

(i) Prior to and upon enrollment in the PACE organization.

* * * * *

(3) To examine, or upon reasonable request, to be helped to examine the results of the most recent review of the PACE organization conducted by CMS or the State administering agency and any plan of correction in effect.

(c) * * *

(3) 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 as set forth in § 460.162(a).

* * * * *

■ 30. Section 460.116 is amended by revising paragraphs (c)(1) and (2) to read as follows:

**§ 460.116 Explanation of rights.**

* * * * *

(c) * * *

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

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

**§ 460.120 [Amended]**

■ 31. Section 460.120 is amended in paragraph (f) by removing the phrase ''quality assessment and performance improvement'' and adding in its place the phrase ''quality improvement''.

■ 32. Section 460.122 is amended by revising paragraphs (c)(1) and (i) to read as follows:

**§ 460.122 PACE organization's appeals process.**

* * * * *

(c) * * *

(1) Timely preparation and processing of a written denial of coverage or payment as provided in § 460.104(d)(2)(iv).

* * * * *

(i) *Analyzing appeals information.* A PACE organization must maintain, aggregate, and analyze information on appeal proceedings and use this information in the organization's internal quality improvement program.

■ 33. Subpart H is amended by revising the heading to read as follows:

## Subpart H—Quality Improvement

■ 34. Section 460.130 is amended by revising paragraph (a) and adding paragraph (d) to read as follows:

**§ 460.130 General rule.**

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

* * * * *

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

■ 35. Section 460.132 is amended by revising the section heading and paragraphs (a) and (c)(3) to read as follows:

**§ 460.132 Quality improvement plan.**

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

* * * * *

(c) * * *

(3) Document and disseminate to PACE staff and contractors the results from the quality improvement activities.

**§ 460.134 [Amended]**

■ 36. Section 460.134 is amended in the section heading and paragraph (a) introductory text by removing the term ''quality assessment and performance improvement'' and adding in its place the term ''quality improvement''.

**§ 460.136 [Amended]**

■ 37. Section 460.136 is amended by—

■ a. In the section heading and paragraphs (b), (c) introductory text, (c)(1), and (c)(2) by removing the term ''quality assessment and performance improvement'' and adding in its place the term ''quality improvement''.

■ b. In paragraphs (a) heading and (b) heading by removing the term ''Quality assessment and performance improvement'' and adding in its place the term ''Quality improvement''.

**§ 460.138 [Amended]**

■ 38. Section 460.138 is amended in paragraph (b) by removing the term ''quality assessment and performance improvement'' and replacing it with ''quality improvement''.

**§ 460.140 [Removed]**

■ 39. Section 460.140 is removed.

■ 40. Section 460.150 is amended by revising paragraph (c)(2) to read as follows:

**§ 460.150 Eligibility to enroll in a PACE program.**

* * * * *

(c) * * *

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

* * * * *

■ 41. Section 460.152 is amended by revising paragraph (b)(4) to read as follows:

**§ 460.152 Enrollment process.**

* * * * *

(b) * * *

(4) Notify CMS and the State administering agency in the form and manner specified by CMS and make the documentation available for review.

■ 42. Section 460.154 is amended by revising paragraph (i) to read as follows:

**§ 460.154 Enrollment agreement.**

* * * * *

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

* * * * *

■ 43. Section 460.156 is amended by revising paragraph (a)(2) and removing paragraph (a)(4) to read as follows:

**§ 460.156 Other enrollment procedures.**

(a) * * *

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

* * * * *

■ 44. Section 460.162 is revised to read as follows:

**§ 460.162 Voluntary disenrollment.**

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

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

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

■ 45. Section 460.164 is amended—

■ a. By redesignating paragraphs (a) through (e) as paragraphs (b) through (f), respectively;

■ b. By adding new paragraph (a);

■ c. By revising newly redesignated paragraph (b)(1);

■ d. By redesignating newly redesignated paragraphs (b)(2) through (6) as paragraphs (b)(4) through (8), respectively;

■ e. By adding new paragraphs (b)(2) and (3);

■ f. In newly redesignated paragraph (b)(4) by removing the reference ''paragraph (b)'' and by adding in its place the reference ''paragraph (c)''; and

■ g. By revising newly redesignated paragraphs (c) and (d).

The revisions and additions read as follows:

**§ 460.164 Involuntary disenrollment.**

(a) *Effective date.* A participant's involuntary disenrollment occurs after the PACE organization meets the requirements set forth in this section and is effective on the first day of the next month that begins 30 days after the day the PACE organization sends notice of the disenrollment to the participant.

(b) * * *

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

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

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

* * * * *

(c) *Disruptive or threatening behavior.* (1) For purposes of this section, a participant who engages in disruptive or threatening behavior refers to a participant who exhibits either of the following:

(i) A participant whose behavior jeopardizes his or her health or safety, or the safety of others; or

(ii) A participant with decision-making capacity who consistently

refuses to comply with his or her individual plan of care or the terms of the PACE enrollment agreement.

(2) For purposes of this section, a participant's caregiver who engages in disruptive or threatening behavior exhibits behavior that jeopardizes the participant's health or safety, or the safety of the caregiver or others.

(d) *Documentation of disruptive or threatening behavior.* If a PACE organization proposes to disenroll a participant based on the disruptive or threatening behavior of the participant or the participant's caregiver, the organization must document the following information in the participant's medical record:

(1) The reasons for proposing to disenroll the participant.

(2) All efforts to remedy the situation.

* * * * *

■ 46. Section 460.166 is amended by revising the section heading to read as follows:

**§ 460.166 Disenrollment responsibilities.**

* * * * *

■ 47. Section 460.168 is amended by revising paragraph (a) to read as follows:

**§ 460.168 Reinstatement in other Medicare and Medicaid programs.**

* * * * *

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

* * * * *

**§ 460.172 [Amended]**

■ 48. Section 460.172 is amended in paragraph (c) by removing the reference ''quality assessment and performance improvement'' and adding in its place the reference ''quality improvement''.

■ 49. Section 460.182 is amended by revising paragraph (b) introductory text to read as follows:

**§ 460.182 Medicaid payment.**

* * * * *

(b) The monthly capitation amount is negotiated between the PACE organization and the State administering agency, and the amount, or the methodology used to calculate the amount, is specified in the PACE program agreement. The amount represents the following:

* * * * *

■ 50. Section 460.190 is amended by—

■ a. Revising paragraph (b)(1);

■ b. Redesignating paragraphs (b)(2) through (4) as paragraphs (b)(3) through (5); and

■ c. Adding a new paragraph (b)(2).

The revision and addition read as follows:

**§ 460.190 Monitoring during trial period.**

* * * * *

(b) * * *

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

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

* * * * *

■ 51. Section 460.192 is amended by revising paragraph (b) to read as follows:

**§ 460.192 Ongoing monitoring after trial period.**

* * * * *

(b) CMS in cooperation with the State administering agency will conduct reviews of the operations of PACE organizations as appropriate, as determined by a risk assessment of each PACE organization which takes into account the PACE organization's performance level and compliance with the significant requirements of sections 1834 and 1934 of the Social Security Act and this part.

■ 52. Section 460.194 is amended by revising paragraph (a) to read as follows:

**§ 460.194 Corrective action.**

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

(1) Ongoing monitoring of the PACE organization.

(2) Reviews and audits of the PACE organization.

(3) Complaints from PACE participants or caregivers.

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

* * * * *

■ 53. Section 460.196 is amended by revising paragraph (d) to read as follows:

**§ 460.196 Disclosure of review results.**

* * * * *

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

■ 54. Section 460.200 is amended by revising paragraphs (f)(1)(ii) and (iii) to read as follows:

**§ 460.200 Maintenance of records and reporting of data.**

* * * * *

(f) * * *

(1) * * *

(ii) Ten years from the last entry date.

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

* * * * *

Dated: March 15, 2019.

**Seema Verma,**

*Administrator, Centers for Medicare & Medicaid Services.*

Dated: April 3, 2019.

**Alex M. Azar II,**

*Secretary, Department of Health and Human Services.*

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