DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 423 and 460

[CMS–4168–P]

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: Proposed rule.

SUMMARY: This proposed rule would revise and update the requirements for the Programs of All-Inclusive Care for the Elderly (PACE) under the Medicare and Medicaid programs. The proposed 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 The proposed changes would provide greater operational flexibility, remove redundancies and outdated information, and codify existing practice.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 17, 2016.

ADDRESSES: In commenting, please refer to file code CMS–4168–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions for ''submitting a comment.''

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4168–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4168–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments before the close of the comment period to the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members. Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the close of the comment period.

FOR FURTHER INFORMATION CONTACT: Martha Hennessy, 410–786–0575.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Timely received comments will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

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Acronyms

Because of the many terms to which we refer by acronym in this proposed rule, we are listing the acronym and its corresponding term in alphabetical order below:

BBA Balanced Budget Act of 1997
BIPA Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000
CMP Civil Money Penalty
CMS Centers for Medicare & Medicaid Services
COBRA Consolidated Omnibus Budget Reconciliation Act of 1985
GAO Government Accountability Office
HHS U.S. Department of Health and Human Services
HPMS Health Plan Management System
IDT Interdisciplinary Team
IFC Interim Final Rule with Comment Period
MA Medicare Advantage
MAO Medicare Advantage Organization
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003
MSP Medicare Secondary Payer
OBRA Omnibus Budget Reconciliation Act
OIG Office of Inspector General
PACE Programs of All-inclusive Care for the Elderly
PCA Personal Care Attendants
PDP Prescription Drug Plan
PO PACE Organization
SAA State Administering Agency
SSA Social Security Act

I. Executive Summary

A. Purpose

The purpose of this proposed 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 proposals address 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 proposed changes would 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. As is authorized by sections 1934(f)(3) and 1894(f)(3) of the Social Security Act (the Act), we are now proposing to adopt two key elements of the Part D compliance program in the PACE regulations. Specifically, we would require each PACE organization (PO) to develop compliance oversight requirements that would be responsible for monitoring and auditing their organization for compliance with our regulations. Additionally, we would require POs to have measures that prevent, detect and correct non-compliance with CMS's program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. This mirrors what POs are currently required to do for their Part D operations and would simply extend the requirement to all of the PO's operations. We believe by creating a uniform requirement for all of the PO's operations, we are balancing the duty of a PO to ensure compliance with CMS requirements with the need for flexibility as a provider of service.

2. Monitoring and Oversight of PACE Organizations

As a result of our experience with oversight and monitoring of the PACE program, we are proposing 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 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 are proposing therefore to use technology to enhance efficiencies in monitoring by remotely reviewing PO documents, which we have to date reviewed primarily through site visits. We would reduce the number of onsite visits after the 3-year trial period by utilizing a risk assessment to select which POs will be audited each year. This risk assessment would rely largely 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.

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)
Proposed Compliance Oversight Requirements.	We estimate a one-time cost of $353,668 per year, annualized for 3 years, for developing the written material and documents necessary for internal auditing and monitoring programs (119 PO × 150 hours per PO × 59.44 (hourly rate) divided by 3 (annualized over 3 years)). We further estimate an annual cost of $1,414,672 per year to update materials and for routine identification of risks (119 PO × 200 hours per PO × 59.44 hourly rate). Thus total cost would be $1.7 million in years 1 through 3 and $1.4 million afterwards.	
Monitoring	We estimate that there will be an annual savings to POs based on our proposal of $707,617.60. We expect 72 PO audits under the current regulations. We expect only 35 audits if the proposed regulation is finalized. 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 $19,124.80 (2 Health Service Managers at $50.99/hour × 2 (Factor for fringe benefits) × 80 hours per person plus 1 executive administrative assistant at $17.55/hour × 2 (Factor for fringe benefits) × 80 hours per person). Therefore the total savings to POs will be $19,124.80 × 37 = $707,617.60.	We estimate an annual savings of $1,029,455 to the government. We expect 72 PO audits under current regulations. We expect only 35 audits if the proposed regulation is finalized. The savings to us would be the effort saved by not having to perform 37 audits. The cost per audit is 2.5 FTE × $1,395 air-fare + 220 hours for GS–13s × $44.15/hr GS–13 wage × 2 (Fringe benefit factor) + 40 hours for GS–15s × $61.37/hr GS–15 wage × 2 (Fringe benefit factor) = $27,823. Hence the total savings is $27,832 × 37 = 1 million.

II. Background

A. Program Description

The Programs of All-Inclusive Care for the Elderly (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 interdisciplinary team (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 onsite 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 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–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 interdisciplinary team 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. Provisions of the Proposed Rule

In this proposed rule, we are proposing 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. PACE has proven successful in keeping frail, older individuals, many of whom are eligible for both Medicare and 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 are proposing a number of flexibilities in this rule, 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.

A. Proposed Global Change Regarding Quality Assessment and Performance Improvement

Part 460 encompasses all of the regulatory provisions pertaining to PACE. We are proposing 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 are proposing 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 Medicare Advantage Quality Improvement Program, so this change would allow for consistency in use of language across CMS programs. This would be a change in terminology only and would not designate a change in the requirements for the PACE quality program. While we are proposing to implement this change in every place that contains the term ''quality assessment and performance improvement'', we are only discussing our rationale for this proposed change in this section of the preamble. This proposed 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), and (c), 460.138(b), and 460.172(c), and the headings of subpart H and §§ 460.132, 460.134, and 460.136. As discussed in section III.I.3., we are proposing to remove § 460.140 in its entirety, so we would not need to change the reference in that section.

B. Subpart A—Basis, Scope, and Definitions

1. Proposed 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 are proposing 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 part 423. 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,

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

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

[3] 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/documents/reports/jun12_entirereport.pdf.*

see section 2.5 of the Part D Application for new POs, available at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ApplicationGuidance.html.*) We believe this 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.

C. Subpart B—PACE Organization Application and Waiver Process

1. Purpose (§ 460.10)

In this section, we propose changes to part 460, subpart B. 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 are proposing to revise this section to add a new paragraph (a) to address the application process and a new paragraph (b) in which we are proposing to move the current language in this section regarding the waiver process.

As discussed in section III.C.2. of this proposed rule, we are proposing to revise the regulations in subpart B to describe the process for a PO to seek approval from CMS to expand a service area and/or add a new PACE center site. Therefore, we are proposing to amend § 460.10 by adding language regarding the application procedures for expanding an existing service area and/or adding a new PACE center site. This section would still introduce the subpart that sets forth the application procedures for applying to become a PO.

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, available at *http://www.medicaid.gov/medicaid-chip-program-information/by-topics/long-term-services-and-supports/integrating-care/program-of-all-inclusive-care-for-the-elderly-pace/pace-4-states.html.* This application is 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 are proposing amending § 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 are proposing 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 believe 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 are proposing 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 is currently required. These applications are 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. 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 have successfully transitioned the Medicare Advantage application and Prescription Drug Plan (PDP) application to a fully electronic submission process, enabling a more organized and streamlined review, and would like to bring those same efficiencies to the PACE application process. We will provide further guidance on this process through HPMS or similar electronic system that may replace HPMS. POs and applicants may also refer to the CMS online tools for application submission at *http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Long-Term-Services-and-Supports/Integrating-Care/Program-of-All-Inclusive-Care-for-the-Elderly-PACE/Program-of-All-Inclusive-Care-for-the-Elderly-PACE.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, we are proposing 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 are proposing 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 want entities to understand that 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 be a PO and is willing to enter into a PACE program agreement with the entity. We would not review applications that do not include this assurance.

Similarly, we are also proposing 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 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.

We also are proposing 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. In proposed § 460.12(c)(1), we 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 propose 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's 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 are proposing 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.

We believe all of these changes to § 460.12 would streamline the regulations and make the requirements clear, consistent with the PACE statutes. If we finalize these proposals, we will provide subregulatory guidance on application submission requirements after publication of the final rule.

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 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 are proposing 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. 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 service area expansion application might include information obtained from financial reviews, as well as the results from ongoing monitoring visits. Therefore, we propose 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. 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 are also proposing 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.''

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 are proposing 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 are proposing 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.

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's 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 CMS has 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's 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 are proposing to codify CMS's current sub-regulatory requirements for notifying POs of CMS's determination regarding service area and PACE center site expansion applications so the regulations include all of the relevant application timing requirements. Specifically, we are proposing 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 are proposing 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 believe it is confusing to state that an application is complete if we are requesting additional information. Therefore, we are proposing to delete § 460.20(a)(3), which is the provision that describes CMS requesting additional information needed to make a final determination, and 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. Note that we would not consider the application complete without the required state assurance. We also propose 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 are proposing that § 460.20(b) through (d) be redesignated as § 460.20(c) through (e) and revised as follows. We are proposing that new § 460.20(c) 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 are proposing 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 would consider the State Readiness Review, 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 ask for its submission in all requests for additional information if we did not already have this information. Further, if more than 6 months elapse between the date of submission of the application and the response to the 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 propose to revise § 460.20(c) accordingly.

Section 460.20(b), which we are proposing 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 are proposing to amend the language in this provision to address the different time limits for expansion applications. We are also proposing 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. With the proposed changes to § 460.20(a) and the proposed addition of § 460.20(b), it is no longer necessary to describe CMS's review process after all requested information has been received; thus we would remove § 460.20(b)(1) and (2). Section 460.20(c), which we are proposing 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 are proposing to amend this language to specify deemed approval will occur if CMS fails to act after the later of those dates, and that it only applies to entities submitting applications to become a PO, not expansion applications from existing POs. We believe this revision is necessary because, as described previously, we are proposing to address expansion applications in the regulations, and we want 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. CMS does not currently employ ''deemed approval'' for expansion applications, and we do not believe there is any reason to do so for these applications at this time. We are further proposing 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 proposed amendments to § 460.20(a) and (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 are proposing 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.

5. Service Area Designation (§ 460.22)

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

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

Section 460.26 sets forth the process for submitting and evaluating waiver requests. We are proposing 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. 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 are not proposing any policy changes with these proposed revisions, we believe these changes would make the requirements for submission of the waiver request more concise and clear. 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 are proposing 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).

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

Section 460.28 discusses the time frames for CMS determination and notification regarding approval or denial of waiver requests. 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 are proposing 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 propose 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 are proposing these changes to reflect how we provide notification, whether it be electronically or in another format. It should be noted that CMS would not only provide notification verbally. We propose to redesignate § 460.28(a)(2) as new § 460.28(a)(3).

We propose 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. Under CMS's 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. 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 will either receive an approval or denial.

In addition, we are proposing to remove the language in § 460.28(b) regarding the date of receipt of the waiver, because our 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 are also proposing 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). CMS will notify POs to confirm receipt of ''complete'' waiver requests.

We are proposing new language in § 460.28(b) regarding additional information requests for waivers. 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). Although we cannot stop the clock, we believe the statute can be read to start the 90-day clock upon CMS's receipt of a complete waiver request. We therefore are proposing 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. If CMS determines that 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 are proposing 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. Further, we believe 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 proposed process, 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.

This is similar to the proposed treatment of PACE applications, and we believe consistency in review procedures would be helpful to all parties involved. We also note 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 propose 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 are proposing to redesignate this provision as paragraph (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 are proposing 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 are proposing 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. 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 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.

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 believe it is not always practical to include the actual Medicaid capitation rates in the PACE program agreement. Therefore, we are proposing 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 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.

We are also interested in seeking, more generally, 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 are particularly interested in comments regarding the need for capturing the level of detail currently required within the agreement itself, along with updated information as may be necessary throughout the contract period. Much of the required program agreement content relates to operational components of the PO's program. 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, in accordance with regulation and guidance, and are consistently employed. We request comment on whether specific policies and procedures, and other existing requirements should continue to be part of the PACE program agreement.

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 are proposing 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. While current regulations reflect CMS and the SAA's authority to terminate an organization in these circumstances, we believe that we need to clarify our authority with respect to alternative enforcement actions in the form of sanctions or civil money penalties (CMPs).

We propose 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. Consistent with the authorizations in sections 1894(e)(6)(B) and (f)(3) and sections 1934(e)(6)(B) and (f)(3) of the Act, this new provision aligns the PACE enforcement structure with the enforcement structure that applies to the Medicare+Choice program, renamed, and hereinafter referred to, as the Medicare Advantage program. The Medicare Advantage 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 propose that this authority also be utilized in the PACE program, consistent with our statutory authority identified in section 1894(c)(6)(B) and 1934(e)(6)(B) of the Act to promote consistency with the enforcement structure of the Medicare Advantage program. This change will 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 are proposing to redesignate the introductory language in § 460.40 as paragraph (a) and redesignate paragraphs (a) through (i) as paragraphs (a)(1) through (9).

2. Civil Money Penalties (§ 460.46)

Due to the redesignation of paragraphs in § 460.40, we also are proposing to make technical, non-substantive changes to the citations in this section to reflect the substantive and technical changes discussed above.

Specifically, we are amending § 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 are proposing 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 are also proposing 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 in this proposed rule.

Additionally, we are adding a new note to § 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 42 CFR 1003.102. To ensure transparency, we have added a note stating that the penalty amounts are adjusted for inflation and citing to 42 CFR 1003.102.

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:

1. 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).

2. The population enrolled with such entities is less frail than the population enrolled with other POs.

3. 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.

4. 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.[4] 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 material that provided insight into the first and second BBA statements.[5] 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 can be found 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, we are proposing to remove the corresponding restriction in § 460.60(a) in its entirety. We propose to redesignate § 460.60(b), (c), and (d) as § 460.60(a), (b), and (c).

In addition, we propose 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 changes of ownership. 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 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 change in ownership (see PACE Manual, Ch. 2, section 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 change of ownership. In the 2006 final rule (71 FR 71264), we discussed the comments we

[4] 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.*

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

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 change of ownership, we would apply the general provisions described in the Medicare Advantage regulations at § 422.550.

Based on our experiences with PO changes of ownership since we published the 2006 final rule, we no longer believe 14 days gives us enough time to review and process a change of ownership. A change of ownership is significantly different from other organizational changes in that it results in the acquiring entity assuming the responsibilities under the PACE program agreement. We need additional time to determine whether the acquiring entity meets statutory and regulatory requirements for entering into a PACE program agreement. 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, the process to effectuate a change of ownership 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 want 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 change of ownership scenario. Therefore, we propose to amend newly redesignated paragraph (c)(3) to indicate that the 14-day timeframe does not apply to changes of ownership, and to add new paragraph (d), which would specify that a PO planning a change of ownership 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 believe this will provide the time we need to determine if the entity acquiring the PO meets all PACE requirements and will be able to continue providing quality care to the participants of the PO, and to reflect the change in our systems. We also believe the amended language would provide greater clarity to POs as to the requirements that will apply in change of ownership scenarios. We believe the Medicare Advantage requirements for changes of ownership in 42 CFR part 422, subpart L, are appropriate for the PACE program. We will only enter into a PACE program agreement with an entity that is determined to meet PACE program requirements.

For the purposes of this provision, any change of ownership 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. POs will need to follow all change of ownership 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's 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.

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 are proposing 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 previously in section II.A. of this proposed rule, we are also proposing 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.

In addition, as discussed later in this section, we are proposing 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 believe adoption and implementation of compliance oversight requirements is the responsibility of the governing body. 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 are proposing 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.

3. Proposed 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. As is authorized by sections 1934(f)(3) and 1894(f)(3) of the Act, we are now proposing to adopt compliance oversight requirements in the PACE regulations. Specifically, we would 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 would require POs to have measures that prevent, detect and correct non-compliance with CMS's program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. This is a proposed new section at § 460.63, entitled ''Compliance Oversight Requirements.''

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 proposed in this regulation.

In § 460.63, we propose 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 propose to require each PO to adopt and implement effective compliance oversight, which includes measures that prevent, detect and correct non-compliance with CMS's program requirements as well as measures that prevent, detect and correct fraud, waste and abuse. We propose that the compliance oversight program in PACE include, at a minimum: (1) The establishment and implementation of an effective system for routine monitoring and identification of compliance risks, which should include internal monitoring and audits and, as appropriate, external audits, to evaluate the PO, including contractors, compliance with CMS requirements and the overall effectiveness of the compliance oversight program; and (2) the establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensuring ongoing compliance with our requirements. Included in this proposal would be the requirements that a PO: (1) Conduct a timely and reasonable inquiry if evidence of misconduct relating to payment or delivery of items or services is discovered, (2) conduct appropriate corrective action in response to potential violations (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. The PO should already have these elements implemented for their Part D benefit, but they would need to expand these efforts to cover all of the services provided by the PO.

POs are not currently required to conduct internal organization wide monitoring or auditing efforts. Through our experiences with MA and Part D organizations, we believe that conducting monitoring and auditing is key to identifying and correcting issues of non-compliance with CMS requirements. We believe 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. POs will also benefit from improving their ability to identify and correct compliance risks within their own organization.

Additionally, our proposal requires the PO to implement appropriate corrective action in response to any identified issues of non-compliance that POs may discover. These elements are important safeguards to protect against fraud, waste, and abuse, and to ensure POs are compliant with CMS requirements. We believe our proposal for POs to adopt these compliance oversight requirements is a reasonable approach and will ensure POs are identifying and correcting potential non-compliance at the earliest possible stage.

If finalized, we intend to verify compliance with this new requirement through monitoring or auditing of the PO.

4. Personnel Qualifications (§ 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, 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.

We believe that 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. 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 are proposing 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 PACE organization on working with a frail or elderly population upon hiring. This proposal 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. 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 do not believe it is necessary for CMS to approve those competency evaluation programs prior to their use. CMS expects the PO to use current industry standards. Therefore, we propose to revise to this paragraph to remove the reference to CMS approval. We also are proposing 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.

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 in order 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 are proposing 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. We believe including all of the related requirements in the same section would reduce confusion over applicable requirements. We are not proposing any changes to the language in § 460.66(a) but are proposing to remove the paragraph designation of paragraph (a).

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 who 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 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 use.

We believe that 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 are proposing to amend § 460.68(a) by adding clarifying language to current paragraph (a)(3) and by adding two new paragraphs (a)(4) and (5).

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 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 DUI convictions. We believe 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 (see, for example, § 483.13(c)(1)(ii)), where specific restrictions are focused on individuals that are found guilty of abusing, neglecting or mistreating nursing home residents.

As such we are proposing 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 note 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 note 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. We are therefore proposing to amend the language to include ''drug, or alcohol abuse or use.''

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 are proposing to add language in paragraphs (a)(4) and (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 are proposing 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 § 483.13(c)(1)(ii). We believe 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 are proposing 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 are proposing to add two paragraphs to the current three paragraphs in paragraph (a), we are proposing to remove the word ''or'' at the end of paragraph (a)(2). We also invite public comment on whether we should extend this provision to restrict hiring with respect to those with certain criminal justice histories to also include those 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. We are seeking input 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. 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. Because POs already support the majority of participants in non-institutional settings, we are seeking comments on whether or not CMS should apply the requirements to POs. Although we are not proposing any changes in this proposed rule requiring compliance with § 441.301(c)(4) when non-institutional settings used to house and/or provide services to PACE participants, we are requesting comments on possible proposals to do so in future rulemaking. Changes we are considering and on which we are soliciting comments include:

- Adding a new paragraph § 460.70(b)(1)(iv) stating, a contractor must comply with the Home and Community-Based Settings (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 Home and Community-Based Settings (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.

In this proposed rule, we are proposing 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. Although the current provisions do not explicitly reference those individuals, this was our intent when we adopted the requirements in the 2002 IFC (see 67 FR 61498, 61505) and when we addressed these requirements in the 2006 final rule (see 71 FR 71270, 71335). 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 are proposing to add a new paragraph (d)(6) under which we are proposing 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 are also proposing 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 are proposing 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 are also proposing to revise § 460.70(e)(2) to correct the reference contained in that section by changing § 460.98(d) to be § 460.98(c).

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 are proposing to make some technical, non-substantive changes to paragraph (a)(1) that would make the provision more concise. We are also proposing to amend paragraph (b)(4). 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 (see 71 FR 71273). We note that § 460.71(b)(4) was not amended in a consistent manner, which we understand caused confusion among POs about whether to attach the same meaning to ''medically cleared for communicable diseases'' and ''free of communicable diseases.'' Therefore, we are proposing to amend § 460.71(b)(4) by referencing the language previously added to § 460.64(a)(5) so that both sections are consistent and contain the same language.

As noted previously in our discussion of proposed changes to § 460.66, we propose to move paragraphs (b) and (c) of § 460.66 related to direct participant care to § 460.71(c) and (d), respectively.

9. Physical Environment (§ 460.72)

Section 460.72 addresses requirements for the physical environment of the PACE center, including those pertaining to space and equipment, fire safety, and emergency and disaster preparedness. CMS previously issued a proposed rule under the Medicare and Medicaid programs that, if finalized, would affect the PACE requirements at § 460.72. Specifically, in the December 27, 2013 **Federal Register** (78 FR 79802), CMS published a proposed rule titled ''Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers; Proposed Rule.'' The rule proposed to establish 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. Regarding PACE, the proposed rule generally would remove the current PO emergency preparedness requirements at § 460.72(c)(1) through (5) and incorporate them into a new proposed § 460.84, ''Emergency preparedness.'' For a complete discussion of the PACE emergency preparedness proposal, see 78 FR 79107 through 79108, 79185.

As with all rulemaking, the public was afforded an opportunity to comment on these proposed revisions during the notice and comment period. CMS intends to address the comments and any changes to the PACE program through that rulemaking and not in this proposed rule.

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 are proposing to further clarify this requirement by defining what we mean by ''principal languages of the community.'' As we stated in the 2006 final rule (71 FR 71279), we believe the determination of a principal language of the community is a state determination. However, we recognize 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 are proposing 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. We refer 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 established a similar 5 percent language threshold for marketing materials in the Medicare Advantage program (see § 422.2264(e)), and we believe this threshold is also appropriate for PACE. Moreover, we strive to create harmony across program requirements when feasible. This reduces complexity for those organizations that operate multiple CMS programs. Currently, in the Medicare Advantage 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. If we finalize this proposal, we would use the same approach in PACE. We note that our proposal does not aim to replace any state-based language thresholds; rather the goal is to provide a standard in instances where a state standard does not exist. Additionally, this proposal 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 it aims to set a more clear standard for when furnishing such materials is a requirement.

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 2006 final rule, this provision does not prevent a PO from offering gifts of a nominal value (see 71 FR 71279). For example, as we explained in the 2006 final rule, offering gifts to potential enrollees that 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 are proposing 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. 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 believe this 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. Similar flexibility has been permitted under both the Medicare Advantage and Part D programs for several years with no notable adverse impact to participants. As such, 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 Medicare Advantage and Part D programs, the PACE regulatory definition of a nominal gift will 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 believe it is in the best interest of the program to only permit POs to market their programs through their own employees. Therefore, we are proposing amendments to this section to specifically prohibit POs from using non-employed agents/brokers, including contracted entities, to market PACE programs.

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. 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 Prescription Drug Plan (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. We are concerned 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. It is important to emphasize that our concern is 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 believe employees of the PO are 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. 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.

We believe that only permitting POs to use employees for marketing activities will 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 are proposing to amend § 460.82(e) to remove the term ''agents'' and simplify the language. The revised provision would state that a PACE organization must not use the following marketing practices, which are prohibited. In conjunction with that revision, we are also proposing to amend paragraph (e)(4) to prohibit marketing by any individuals other than the employees of the PACE organization. We realize that some POs have existing arrangements with independent agents and brokers. We also recognize that, as with other functions, POs may delegate such responsibilities to an outside entity. Therefore, we are seeking comment as to whether CMS's proposed prohibition on the use of independent agents and brokers is appropriate. If commenters believe that this prohibition is not appropriate, we ask for 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.

Section 460.82(e)(5) prohibits unsolicited door-to-door marketing. We are proposing 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. 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). 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 (see 71 FR 71279). Based on the vulnerability of the population served by the PACE program and the increase in health care fraud that we have seen since 2006, we believe a prohibition on other unsolicited means of direct contact is appropriate for PACE. Moreover, such a prohibition is consistent with our marketing requirements for MA organizations (see § 422.2268(d)) and PDP sponsors (see § 423.2268(d)).

We are also proposing 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. Based on the insight we have gained through years of oversight responsibility for the PACE program, we believe the requirement for a marketing plan is redundant. We believe 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. The CMS Account Manager is 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.

G. Subpart F—PACE Services

1. Service Delivery (§ 460.98)

Section 460.98 addresses service delivery under PACE. We propose 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 would replace ''Pace center'' with ''PACE center'' for the same reason.

In addition, we are requesting public comment 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(b)(2), 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 explained in 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, which helps to differentiate it from home health care or institutional care. 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.

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 as well as inhibit expansion of existing programs. To better understand the issues facing POs, we invite 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 for this population. 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.

2. Emergency Care (§ 460.100)

Section 460.100 addresses emergency care under PACE. We are proposing 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.

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 (see 64 FR 66248). As we have stated previously in preambles to rules and subregulatory guidance (see *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). 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 understand 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 are proposing that a PO be permitted to have one individual fulfill a maximum of 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, 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. Pursuant to §§ 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. 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 are proposing 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 are proposing to revise paragraph (b) to state the IDT must be composed of members qualified to fill at a minimum the following roles, in accordance with CMS guidelines. We will publish the IDT guidelines in HPMS following publication of the final rule. 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.

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. 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 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 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 1999 IFC (64 FR 66248) and the 2006 final rule (71 FR 71285), the role of primary care physician role 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 stated 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 rule of the primary care physician consistent with state licensure requirements for nurse practitioners.

As discussed previously in this proposed rule, the PACE program agreement has replaced the PACE Protocol. As with certain other requirements that were based on the PACE Protocol, we believe the composition of the IDT needs to change to reflect evolving medical practices and technologies. We believe it is appropriate to expand the primary care physician role on the IDT to include certain other primary care providers. Accordingly, we are now proposing 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 are proposing 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 are also proposing that § 460.102(c)(2) refer to primary care provider rather than primary care physician. These proposed 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 are proposing 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. With increasing shortages of primary care providers across the country, we believe 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 propose redesignating the current language in paragraph (e) as paragraph (f) and, in a new paragraph (e), we propose 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. 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, 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.

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 authorized 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 are proposing to revise § 460.102(c)(1) to allow community-based physicians to fill the role of primary care provider on the IDT. 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 many times patients in those community settings become PACE participants. Newly enrolled PACE participants often request to continue receiving care from their community-based physician. We want to allow this flexibility for PACE participants because we believe it supports the continuity of care for participants. We therefore are proposing 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. Under this proposal, community-based physicians would be able to continue working in their community settings while contracting with the POs to provide PACE services. This proposal, in combination with the proposed revision to paragraph (b)(1), would effectively be a global waiver of the IDT member and ''primarily served'' requirements for community-based primary care physicians.

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. 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 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 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 our proposed revisions to § 460.102(c) discussed previously, 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. These monitoring activities would serve as a safeguard to help ensure there is no negative impact to the quality of care being provided.

We believe 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 invite public comment on this approach.

Similarly, 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 both 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. 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 invite public comment on whether we should extend this flexibility to all POs without the need to request a waiver.

4. Participant Assessment (§ 460.104)

Section 460.104 sets forth the requirements for PACE participant assessments. As we explained in 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. With this proposal, to the extent an IDT member serves multiple roles on the IDT, that member may represent the clinical expertise for which s/he 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 are proposing to add the phrase ''in-person'' after ''initial'' in paragraph (a)(1). 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 are proposing 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.'' 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, which is the timeframe that we are proposing later in this discussion.

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 are proposing 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 proposed rule, we are proposing that the primary care physician role be changed to primary care provider to allow other licensed primary care providers (for example, nurse practitioners, physician assistants, and community-based physicians) to be part of the core IDT.

In § 460.104(a)(2), we are proposing 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 believe stating that they must occur ''at appropriate intervals'' is unnecessary and superfluous language. We are proposing 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 are proposing 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 are proposing 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 are proposing to revise the heading to ''Initial comprehensive assessment criteria.'' We also are proposing to add ''in-person'' to this section to make it consistent with the terminology in § 460.104(a)(1) and (2). We believe that 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.'' 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 are proposing 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 believe that 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, 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 believe 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 are proposing 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 are proposing to create a new paragraph under § 460.104(b). Under new paragraph (b)(1), we are proposing 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. 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. CMS expects 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 are proposing 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 PACE organization'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. 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 are proposing to delete the requirement in paragraph (c)(2) requiring the annual reassessments by the physical therapist, occupational therapist, dietician, and home care coordinator. We are proposing to delete corresponding references to annual reassessments in paragraph (d). We would keep the requirement that PACE participants be reassessed semiannually, every 6 months. 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 believe 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 are proposing to remove ''recreational therapist or activity coordinator'' from the list of IDT members that must participate in the semiannual reassessment. We believe reducing the 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. 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 or 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 believe that 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 do not believe we need 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 paragraphs (c)(1)(i) through (iii) and would be redesignated as paragraphs (c)(1) through (3). In the redesignated paragraph (c)(1), we would revise ''physician'' to ''provider'' for consistency with the proposed revisions previously discussed in this section. We are proposing to redesignate paragraph (c)(1)(v) as (c)(4) and revise the provision to delete the example because we believe the example is unnecessary.

Section 460.104(d) discusses unscheduled reassessments. As discussed previously, we are proposing changes to paragraph (d) to remove the reference to annual reassessments. We are proposing to change the language in paragraph (d)(1) from ''listed in paragraph (a)(2) of this section'' to ''listed in paragraph (c) of this section.'' This proposal 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 are proposing to change paragraph (d)(2) regarding unscheduled reassessments at the request of the participant or the participant's designated representative. Instead of stating that if a participant (or designated representative) believes that the participant needs to initiate, eliminate, or continue a particular service, the appropriate members of the IDT, as identified by the IDT, must conduct an in-person reassessment, the provision would state that if a participant (or designated representative) requests to initiate, eliminate, or continue a particular service, the IDT members specified in § 460.104(c) must conduct an in-person reassessment. As with the semiannual reassessments, we believe reducing the number of IDT members that are required to conduct the unscheduled reassessments will reduce the burden on POs and allow the POs to allocate their resources more efficiently, while still meeting the care needs of participants. Further, we believe that 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 team members should conduct the unscheduled reassessment in this instance. We note that, under § 460.64, 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 would need to involve other IDT members as appropriate. For these reasons, we do not believe we need to require all core members of the IDT to conduct unscheduled reassessments.

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. 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 are proposing to revise this section by adding requirements to provide more clarity without changing the fundamental aspects of the plan of care process.

First, we are proposing 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.'' 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 time frame. This proposed change is consistent with our proposed changes to § 460.104(b), which we discussed previously in this section.

Next we are proposing to add language to clarify which members of the IDT are required to develop the plan of care within 30 days. The proposed language states 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. The added language aims 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. As under current guidance, the IDT remains responsible for developing the plan of care based on the initial discipline-specific assessments.

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 believe 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. Current regulations do not explicitly require POs to follow industry standards in developing and following care plan interventions. We believe that adding new requirements will help POs to effectively and efficiently identify and address each participant's care planning needs. Therefore, we are proposing to add three new requirements to § 460.106(b). In paragraph (b)(3), we are proposing 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 are proposing to require that the plan of care identify each intervention and how it will be implemented. Interventions should be targeted, specific actions implemented to improve a participant's health care outcome. And finally, in paragraph (b)(5), we are proposing to require that the plan of care identify how each intervention will be evaluated to determine progress in reaching specified goals and desired outcomes.

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 are proposing to combine paragraphs (b)(1)(i) and (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 are proposing to make a technical change to § 460.112(b)(3) by deleting the language ''to be assisted'' and replacing it with ''to be helped.'' This proposed change is not a substantive change, but rather an effort to simplify the 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 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 are proposing 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 PACE organization receives the participant's notice of voluntarily disenrollment as set forth in § 460.162(a). As discussed in section III.J.5. of this proposed rule, we are proposing 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. 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.

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 our proposal regarding marketing materials under § 460.82(c)(1), which we discuss in section III.F. of this proposed rule, we are proposing 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 noted previously, we established a similar 5 percent language threshold for marketing materials in the Medicare Advantage program (see § 422.2264(e)), and we believe this threshold is also appropriate for PACE because of the similarities in population make-up between the Medicare Advantage program and PACE. Moreover, CMS strives 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 are proposing to add the word ''PACE'' before the words ''participant rights'' to specify that participant rights specific to PACE must be displayed. 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. The proposed language would explicitly state that the PACE participant rights must be posted in the PACE center.

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) as paragraph (d) in § 460.104, but we inadvertently did not make the corresponding change to the citation referenced in § 460.122(c)(1) (see 71 FR 71292, 71336, and 71337). Therefore, we are proposing 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).

I. Subpart H—Quality Assessment and Performance Improvement

As discussed in section III.A. of this proposed rule, to update the terminology to comport with that used in other CMS programs, we are proposing 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 we are proposing 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 are proposing 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. This proposed change would leave no requirements under § 460.140, so we are also proposing 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 are proposing 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 performance improvement'' with the term ''quality improvement''), we are

proposing to revise paragraph (a) to require a PO to have a written quality improvement plan that is collaborative and interdisciplinary in nature. The PACE program is unique in its structure in that it has a collaborative and interdisciplinary approach in treatment of PACE participants. We believe that 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 physical therapists). 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 believe requiring a collaborative and interdisciplinary quality improvement plan will help POs identify and improve PACE quality issues more appropriately. Therefore, we are proposing 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)

For the reasons discussed in section III.I.1. of this proposed rule, we are proposing to redesignate the content of § 460.140 as § 460.130, and therefore we are proposing to remove § 460.140.

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 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 are proposing 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.

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 are proposing 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.

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 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 are concerned about possible misinterpretations of this provision, and thus are proposing 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.

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 (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 are proposing 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. 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.

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 are proposing to retain this language in new paragraph (b) and add new paragraphs (a) and (c). In paragraph (a), we are proposing 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. 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 PACE organization receives the notice. Thus, the proposed requirement in § 460.162(a) would be consistent with our current practice.

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). Through record review during on-site audits and follow-up to 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 contractor of the PO in an effort to reduce costs for the PO. To help prevent this, we are proposing 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 note 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.

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 are proposing 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 PACE organization sends notice of the disenrollment to the participant. For example, if a PACE organization 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 are proposing to add this requirement to make it clear when a participant's involuntary disenrollment is effective. Additionally, we are proposing to add this requirement to protect participants' due process, as our regulations and guidance do not currently include an advance notice requirement. We note that the PO must not send the disenrollment notice until the SAA has reviewed the proposed involuntary disenrollment and determined that the PO has adequately documented acceptable grounds for disenrollment, as required by current paragraph (e) (proposed paragraph (f)). We believe 30 days would provide sufficient time for an individual to gather documentation, medical records, or other information in order to respond to the PO's proposed disenrollment action, should he or she disagree. Without the 30 days of advance notice, a PO could notify a participant about an involuntary disenrollment late in the month and make the effective date of the involuntary disenrollment the first day of the following month, only a few days away. This would not allow sufficient time for a participant to contest the disenrollment or to effectively coordinate a transition to other care and services.

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 are proposing to redesignate (a)(1) as paragraph (b)(1) and would 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 are proposing the change because we believe 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. The proposed revision would clarify that an involuntary disenrollment cannot be initiated due to a participant's failure to pay until after a 30-day grace period for the participant to pay or to make satisfactory arrangements to pay. 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 are proposing to redesignate paragraphs (a)(2) through (6) as paragraphs (b)(4) through (8) and to add two additional reasons for involuntary disenrollment in new paragraphs (b)(2) and (3). In paragraph (b)(2), we are proposing 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 spenddown 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 spenddown 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 spenddown obligation and post-eligibility treatment of income. Section 460.154(g) requires that a participant that 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 spenddown liability and amount due under the post-eligibility treatment of income process. Operationally, a PO needs the ability to involuntarily disenroll participants based on nonpayment of these amounts. 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 understand 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. CMS has previously addressed this issue for many POs through approval of waivers, but we believe that addressing it through a regulatory change is more efficient and is permitted under the PACE statutes. Moreover, as with any involuntary disenrollment, an involuntary disenrollment based on nonpayment of applicable Medicaid spenddown 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 are proposing to add language that would permit involuntary disenrollment in situations where the participant's caregiver engages in disruptive or threatening behavior. We also are proposing to redesignate current paragraphs (b)(1) and (2) as paragraphs (c)(1)(i) and (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 are proposing 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. This would include any family member involved in the participant's care. We believe that 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. Further, 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 believe could include disruptive or threatening behavior of a caregiver (see 64 FR 66300).

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 have gained more experience with PACE, we realize 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. 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. CMS has 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 where 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. The proposed revision would obviate the need for those waivers, thereby reducing the burden on POs, states, and CMS.

POs must only pursue involuntarily 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 discussed 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 program for which the participant is eligible and must make sure medical records are available to the new providers. This will help ensure that the participant receives needed care. Note that we are not proposing 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.

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 are proposing to change the title to ''Disenrollment responsibilities'' to better describe the subject of this section.

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 are proposing to change ''in a timely manner'' to ''within 30 days,'' which would help ensure a smooth transition for participants. We are proposing 30 days because we believe this balances 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.

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. 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 (4). Consistent with our proposed revisions to § 460.32(a)(12) of this proposed rule, we are proposing to revise § 460.182(b) to require that the PACE program agreement contain the state's Medicaid capitation rate or the ''methodology'' for establishing the Medicaid capitation rates. 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, 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 believe that 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 will 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 are also proposing to redesignate paragraphs (b)(3) and (4) as paragraphs (b)(4) and (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. 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 are proposing 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 believe 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 are also proposing that the monthly capitation amount be consistent with efficiency, economy, and quality of care. By efficiency and economy, we mean 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. 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. 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 would like to solicit comments about other rate methodologies we may consider requiring for Medicaid capitation payment amounts for PACE. We are seeking 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. For example, Medicaid rates for many of the state financial alignment demonstrations require actuarially sound rates. We note, 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 are not proposing changes to the rate methodology for Medicaid capitation payments in this proposed rule; however, we will use public comment to inform possible future PACE rulemaking concerning Medicaid capitation payments.

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 onsite 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 exceeded statutory requirements 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 are proposing to revise these provisions of the existing regulations.

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 no longer believe that the activities listed in § 460.190(b)(1)(i) through (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. The use of this technology has saved significant resources in travel dollars and staff downtime (experienced while they are traveling). Therefore, we are proposing 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 (v). We are also proposing revisions to the language at § 460.190(b)(1) and a new § 460.190(b)(2) to more closely mirror the text of statute. The proposed revised 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. 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 are proposing 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 proposing 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 are retaining the language found in current paragraphs (b)(2), (3), and (4), but propose to redesignate these as paragraphs (b)(3), (4), and (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. 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 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 believe 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 are proposing 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 state administering agency, 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. This risk assessment will rely largely on the organization's past performance and ongoing compliance with CMS and state requirements. However, the risk assessment will 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. 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 or level 2 reporting data complaints, as necessary. We believe using MA and Part D is an appropriate model to mirror PACE audits on, because like in MA and Part D, a PO is responsible for providing a beneficiary's benefits in accordance with our regulations. 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 believe this will be a useful tool in selecting organizations for audit. This proposal, if finalized, would 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, there has been some uncertainty as to which circumstances trigger the requirement that a PO take action to correct deficiencies. We are proposing 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 are proposing 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 are proposing 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)

PACE participants are some of the frailest and most vulnerable members of the Medicare and Medicaid programs, and we recognize 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. We believe 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 are proposing 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 also encourage POs to make review results available to other potential participants and the public, for example, by releasing a summary of the reports online. Posting comprehensive review results online would satisfy PO

requirements under the proposed § 460.196(d).

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; (iii) For medical records of disenrolled participants, 6 years after the date of disenrollment. We are proposing 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. 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 note that POs that offer qualified prescription drug coverage currently must comply with the Medicare Part D record retention requirement in § 423.505(d). The 10-year record retention policy is also consistent with recordkeeping requirements under the Medicaid Drug Rebate Program (§ 447.510(f)). 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, our proposal would extend this requirement to all PACE records for consistency with these programs.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) 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 comment 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.

We are soliciting public comment on each of these issues for the sections of this proposed rule that contain information collection requirements.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2015 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	29.72	29.72	59.44

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent for fringe benefits and support costs. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

In performing estimations, one-time costs and savings are annualized over 3 years.

B. Proposed Information Collection Requirements (ICRs)

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

We are proposing to replace 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), and (c), 460.138(b), and 460.172(c). The change would also affect 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 $59.44/hr for technical staff to replace or amend existing written materials with the updated term. In aggregate, when annualized over 3 years, we estimate a burden of $2,357.79 in each of the 3 years (119 PO × 1 hour × 59.44/hour ÷ 3) The proposed requirements and revised burden will be submitted to OMB under control number 0938–0790 (CMS–R–244).

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 this proposed rule, § 460.12(a) would be revised to specify that this section also applies to expansion applications. This change would codify (in the CFR) the current *Programs of All-Inclusive Care*

for the Elderly (PACE) Manual requirements pertaining to application submissions.

Until recently, a PACE application was submitted in hard copy format. Applications were often hundreds of pages long, expensive to reproduce and transmit, and administratively inefficient. This proposed rule would 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 would provide 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. In this proposed rule, § 460.12(b)(2) would 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 would codify the current PACE manual provisions pertaining to the practice of application submissions.

Section 460.12(c)(1) would require 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, the proposed 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 0938–0790 (CMS–R–244).

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, this proposed rule would 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. It also would clarify 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).

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, this rule proposes to revise 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. The proposed change would 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. Our current burden estimate approved by OMB under control number 0938–0790 (CMS–R–244) accounts for receiving incomplete requests and the submission of additional information.

5. ICRs Regarding the 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 (see §§ 460.32(a)(12) and 460.182(b)). We propose 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 PACE organizations is annually. We do not believe it is always practical or efficient to include the actual Medicaid capitation rates in the PACE program agreement. We also believe this practice provides no value to the PO, the state, or to CMS. In response, we propose 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 going forward that PACE program agreements be updated to include the Medicaid capitation rates, we estimate that each PO would save ½ hour. We therefore estimate an aggregate annual reduction of $3,536.68 (119 PO × 0.5 hour × 59.44 per hour).

The revised requirement will be submitted to OMB for approval under control number 0938–0790 (CMS–R–244).

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 proposed rule would revise 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) would 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).

Section 460.62(a)(8) would be added to require that the PO's governing body must have full legal authority and responsibility for adopting and implementing effective compliance oversight requirements as described in § 460.63. While the requirement to adopt and implement the compliance oversight requirements do not impose any new reporting requirements, the burden associated with the compliance oversight requirements are set out in the Regulatory Impact Analysis section under § 460.63.

7. 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. This proposed rule would amend 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) would not have any effect on the burden that is currently approved by OMB under control number 0938–0790 (CMS–R–244).

8. 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. In this proposed rule, the amendments to § 460.68(a)(3) would 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 are also adding language in § 460.68(a)(4) and (5) similar to the requirements found in regulations governing Long Term Care facilities.

In § 460.68(a)(4), we propose to add a new restriction that would prevent POs from employing 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. Further, in § 460.68(a)(5) we propose 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 policies related to the hiring of individuals with criminal histories and revising their employment applications. We estimate a one-time burden of 10 hr at $59.44/hr for technical staff to make these revisions. In aggregate, we estimate a burden annualized over 3 years of $23,577.87 in each year (10 hours × 119 PO × 59.44 ÷ 3). The proposed requirements and revised burden will be submitted to OMB under control number 0938-New (CMS–0938–0790 (CMS–R–244)).

9. ICRs Regarding Marketing (§ 460.82)

Section 460.82 sets out requirements governing the marketing activities of POs. This proposed rule would prohibit POs from using non-employed agents/brokers, including contracted entities to market PACE programs. We are also proposing to expand the scope of prohibited marketing practices to include additional means of marketing through unsolicited contact. We are also proposing 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. CMS no longer believes that the documented marketing plan provides value 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 $59.44/hr for technical staff to revise the written marketing policies and materials. In aggregate, when annualized over 3 years we estimate $11,788.93 in each year (119 PO × 5 hours × 59.44 ÷ 3).

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 per year. We estimate an aggregate reduction of $70,733.60 in each year (119 PO × 10 hour × 59.44). The proposed requirements and revised burden will be submitted to OMB under control number 0938–0790 (CMS–R–244).

10. ICRs Regarding [the] Interdisciplinary Team (§ 460.102)

Section 460.102 currently states that primary medical care must be furnished to a participant by a PACE primary care physician. This proposed rule would 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.

We estimate a one-time burden of 1 hr at $59.44/hr for technical staff to update their PO's policy and procedures. We estimate an aggregate burden annualized over 3 years of $2357.79 in each year (119 PO × 1 hour × 59.44/hr ÷ 3). The proposed requirements and revised burden will be submitted to OMB under control number 0938–0790 (CMS–R–244).

11. ICRs Regarding [the] 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 rulemaking, we are proposing to remove the requirement in § 460.104(c)(2) requiring annual reassessments by the physical therapist, occupational therapist, dietician, and home care coordinator.

While this requirement was subject to the PRA, we believed that the burden associated with this requirement 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.

12. ICRs Regarding [the] Plan of Care (§ 460.106)

Section 460.106(a) requires that a participant's plan of care be developed by the IDT promptly. This proposed rule would amend this requirement by specifying that the IDT must develop the plan of care within 30 days of the participant's date of enrollment. Section 460.106(b) proposes 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 add clarification to 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. CMS expects POs to keep up-to-date with current practice standards related to plans of care and believes 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 believed 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.

13. 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. The proposed rule requires 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 $59.44/hr for technical staff to revise the written material about participant rights. In aggregate, when annualized over 3 years we estimate $11,788.93 in each year (119 PO × 5 hours × 59.44/hr. ÷ 3).

Section 460.116(c)(2) states that the PO must display the participant rights in a prominent place in the PACE center. The proposed rule would require 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 ½ hr at $59.44/hr for technical staff to revise the notices. In aggregate, when annualized over 3 years we estimate $1,178.89 in each year (119 PO × ½ hours × 59.44/hr. ÷ 3). The proposed requirements and revised burden will be submitted to OMB under control number 0938–0790 (CMS–R–244).

14. 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. This proposed rule would 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. It would also remove in § 460.140 its entirety. This regulatory reorganization has no impact on any requirements or burden estimates.

15. ICRs Regarding Quality Performance Reporting (§ 460.132)

Section 460.132 sets forth requirements with respect to a Quality Assessment and Performance Improvement (QAPI) plan. This proposed rule would revise § 460.132(a) and (c)(3) by referring to 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 $59.44/hr to update material. We estimate it would take in aggregate, when annualized over 3 years, $2357.79 in each year to update QI plans (119 PO × 1 hour × $59.44/hr ÷ 3). The proposed requirements and revised burden will be submitted to OMB under control number 0938–0790 (CMS–R–244).

16. 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. Since this proposed rule would add the phrase, 'in the form and manner specified by CMS'' and would simply codify current practice in which such notifications are submitted to CMS and SAA electronically, this action would not revise any requirements or burden estimates. The requirements and burden are approved by OMB under control number 0938–0790 (CMS–R–244).

17. 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. This proposed rule would 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 $59.44/hr to update enrollment materials. We estimate an aggregate cost, annualized over 3 years, of 2357.79, in each year (119 PO × 1 hour × 59.44/hr). The proposed requirements and burden will be submitted to OMB under control number 0938–0790 (CMS–R–244).

18. 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 propose 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 a decrease of 1 minute for each organization. The aggregate savings would be $117.89 (119 PO × 1 minute × 59.44/hr). The revised requirements and burden will be submitted to OMB under control number 0938–0790 (CMS–R–244).

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.

19. 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. This rule proposes 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 proposed 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).

20. 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. The proposed rule would 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 ½ hr at $59.44/hr for technical staff to redisplay the review results. In aggregate, when annualized over 3 years we estimate $1,178.89 in each year (119 PO × 1/2 hours × 59.44/hr. ÷ 3) in each year.

21. 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. This rule proposes to change this requirement from 6 to 10 years.

The current requirements and burden for storing records for 6 years are approved by OMB under control number 0938–0790 (CMS–R–244). We believe that the burden to store 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.

C. Summary of Annual Burden Estimates for Proposed Requirements

TABLE 3—PROPOSED INFORMATION COLLECTION REQUIREMENTS AND BURDEN *

Section(s) in title 42 of the CFR	OMB Control No.	Respondents	Burden per response (hr)	Cost (+1) or savings (−1)	Cost per hour (hourly wage)	For annual costs: total annual cost (product of 4 columns on right)	For one-time costs: total annualized cost in each of 3 years (product of 4 columns to right of previous column divided by 3)
part 460 (global term change)	0938–0790	119	1	1	$59.44	.....	$2,357.79
460.32 (program agreement)	0938–0790	119	0.5	−1	59.44	(3,536.68)	.....
460.68(a)	0938–0790	119	10	1	59.44	.....	23,577.87
460.82 (revise policies and written materials)	0938–0790	119	5	1	59.44	.....	11,788.93
460.82 (remove requirements)	0938–0790	119	10	−1	59.44	(70,733.60)	.....

TABLE 3—PROPOSED INFORMATION COLLECTION REQUIREMENTS AND BURDEN *—Continued

Section(s) in title 42 of the CFR	OMB Control No.	Respondents	Burden per response (hr)	Cost (+1) or savings (−1)	Cost per hour (hourly wage)	For annual costs: total annual cost (product of 4 columns on right)	For one-time costs: total annualized cost in each of 3 years (product of 4 columns to right of previous column divided by 3)
460.102 (update policies and procedures)	0938–0790	119	1	1	59.44		2,357.79
460.116 (Revise explanations of rights)	0938–0790	119	5	1	59.44		11,788.93
460.116 (Redisplay 'participant rights' as 'PACE participant rights')	0938–0790	119	0.5	1	59.44		1,178.89
460.132 (update QI plan)	0938–0790	119	1	1	59.44		2,357.79
460.154 (revise enrollment agreement)	0938–0790	119	1	1	59.44		2,357.79
460.156 (removing sticker requirement)	0938–0790	119	0.017	−1	59.44	(117.89)	
460.196 (Disclosure of review results)	0938–0790	119	0.5	1	59.44		1,178.89
Total				6		(74,388.17)	58,944.67
Total Cost In each of First 3 years							(15,443.50)
Total Cost in Remaining Years							(74,388.17)

D. Submission of PRA-Related Comments

We have submitted a copy of this proposed 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.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit CMS' Web site at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule and identify the rule (CMS–4168–P) the ICR's CFR citation, CMS ID number, and OMB control number.

PRA-related comments are due October 17, 2016.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the ''**DATES**'' section of the preamble to this proposed rule, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Statement

We have examined the impacts of this proposed 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) and the Congressional Review Act (5 U.S.C. 804(2)).

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 46 provisions. We determined that 21 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 and total less than $800,000 in savings or costs. Of the remaining provisions we believe only 3 of them require scoring in the regulatory impact statement. The provision discussed in section III.K.1. of this proposed rule, proposing modification

of § 460.182 regarding Medicaid payment, has no savings or cost while the provision discussed in section III.F.3. of this proposed rule, proposing § 460.63 regarding the PACE compliance oversight program, has a burden of about 1.7 million dollars to POs. The provision discussed in section III.L.1. of this proposed rule, proposing modification of § 460.190 regarding monitoring, has a savings of about $700,000 to POs and a savings of about 1 million to the government without any transfer to POs. Additionally, as detailed in, CMS–R–244, there is a $3 million burden associated with the collection of information requirements. Thus the net effect of these provisions is minimal (under $2 million). It follows that the net cost or savings of this proposed rule is under $3 million dollars. The total cost by itself is under $5 million and the total savings by itself is under $2 million.

We discuss these provisions in more detail below.

Compliance Oversight Requirements (§ 460.63 (Discussed in Section III.F.3. of This Proposed Rule))

While current regulations do not require POs to implement compliance programs similar to those required in the regulations governing the MA and Part D programs, this rule proposes 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. This PACE proposal would expand the already existing Part D compliance program for POs offering qualified prescription drug coverage under the Part D program to the totality of the PO's operations and would require them 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.

The burden associated with the requirements under § 460.63 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.

We estimate 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 are proposing 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, the PO will have to spend some time going forward monitoring their own compliance, and reporting and responding to any suspected fraud, waste and abuse. We therefore estimate 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 includes the routine monitoring and identification of compliance risks as identified in the course of self-evaluations and audits. We estimate 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 believe this burden to be small, and we believe that 200 hours would cover the ongoing responsibilities of a PO. Included in this 200 hours is PO monitoring of its own compliance; corrective action as a result of that monitoring; and updating PO monitoring measures and procedures.

We are soliciting comments from POs regarding this burden estimate.

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

The proposed 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. The proposed regulatory language was introduced to reflect a requirement that has always been met in practice. In other words, the language reflects existing practices. We therefore do not believe this provision will affect spending at all.

Monitoring (§ 460.190 (Discussed in Section III.L.1. of This Proposed 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 about audits. These assumptions are based on our experience with audits.

- If this provision is not finalized, we assume 72 audits per year, 34 during PO trial periods, and 38 post trial period (routine) audits.
- If this provision is finalized, we estimate 35 audits per year, 20 during PO trial periods and 15 post trial period (routine) audits.

There are several factors involved in these assumptions. For example, if the regulation is not finalized, an audit must be conducted every 2 years post trial period. If the regulation is finalized, routine audits will be conducted based on a risk assessment. We are soliciting comments on our assumptions about audits.

The following further assumptions are used in estimating costs of an audit for a PO.

- *Personnel:* We estimate:
  - 2 Nurse managers with an hourly average wage of $50.99
  - 1 Executive assistant with an hourly average wage of $17.55
- *Hours:*
  - We estimate 80 hours uniformly per person. 40 hours the week before the audit and 40 hours the week of the audit.
- *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. The resulting savings per year to POs is $707,617.60. The calculations are exhibited in Table 4.

TABLE 4—ESTIMATES OF SAVINGS TO POS IF THE PROVISION IN SECTION III.L.1. IS FINALIZED

Item	Per audit	Justification for per audit	If regulation not finalized (72 audits/year—34 during trial period and 38 post trial period)	Justification	If regulation finalized (35 audits/year, 20 during trial period, 15 post trial period)	Justification
Hourly wages, Nurse manager—$50.99.	$16,316.80	80 hours per audit (40, week before, 40, week of) × 2 Nurse managers × $50.99, Hourly wage × 2 (Fringe Benefit factor).	$1,174,809.60	$16,316/audit × 72 audits.	$571,088.00	$16,316.80/audit × 35 audits.
Hourly wages, Executive assistant—$17.55.	2,808.00	80 hours per audit (40, week before, 40, week of) × 2 Nurse managers × $17.55, Hourly wage × 2 (Fringe Benefit factor).	202,176.00	2,808/audit × 72 ...	98,280.00	2,808/audit × 35 audits.
Total Costs	19,124.80	.....	1,376,985.60	.....	669,368.00	
Savings ...	.....	.....	.....	.....	707,617.60	

The following further assumptions are used 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 $44.15
  - 40 hours at the GS–15 level with an hourly average wage of $61.37
- *Fringe Benefits:* We estimate 100 percent (of hourly wage) for fringe benefits
- *Travel costs:* The average cost per trip is $1,395. This is based on our experience across several geographic regions.

Based on these assumptions, we can compute the difference between 72 and 35 audits per year. The resulting savings per year to CMS is $1,029,454.70. The calculations are exhibited in Table 5.

TABLE 5—ESTIMATES OF SAVINGS TO GOVERNMENT (CMS) WITHOUT TRANSFER TO POS, IF PROVISION IN SECTION III.L.1. IS FINALIZED

Item	Cost per audit	Justification for per audit cost	If regulation not finalized (72 audits/year—34 during trial period and 38 post trial period)	Justification	If regulation finalized (35 audits/year, 20 during trial period, 15 post trial period)	Justification
Hourly wage GS 13 ($44.15/hr).	$19,426.00	220 hours/audit × $44.15/hr × 2 (Fringe Benefit factor).	$1,398,672.00	$19,426/audit × 72 audits.	$679,910.00	$19,426/audit × 35 audits.
Hourly wage GS 15 ($61.37/hr).	4,909.60	40 hours/audit × $61.37/hr × 2 (Fringe Benefit factor).	353,491.20	4,909.60/audit × 72 audits.	171,836.00	4,909.60/audit × 35 audits.
Travel	3,487.50	2.5 FTE × $1,395 average cost per trip.	251,100.00	3,487.50 × 72 audits.	122,062.50	3,487.50 × 35 audits.
Total Costs	27,823.10	.....	2,003,263.20	.....	973,808.50	
Savings ...	.....	.....	.....	.....	1,029,454.70	

Based on the above analysis, we have determined that this proposed rule does not reach the economic threshold and thus 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. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by meeting the SBA definition of a small business (having revenues of less than $7.5 million to $38.5 million in any 1 year). Individuals and states are not included in the definition of a small entity. For purposes of the RFA, we estimate 95 percent of POs are nonprofit organizations, and therefore almost all POs are small entities as that term is used in the RFA. However, the proposed requirements would impose negligible cost increases on POs. In addition, the proposed increased flexibility regarding permissible health professionals is likely to be a source of some savings for POs because current regulation that requires some PACE services to be furnished by physicians would be changed to allow those services to be

furnished by non-physician practitioners. The same is true for the provisions which allow IDT members to serve multiple roles as part of the IDT and the additional hiring flexibilities. Therefore, we are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that our proposed changes to this regulation would not have a significant economic impact 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 603 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 proposed 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 2016, that threshold is approximately $146 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 regulation 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 proposed regulation 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 Act requires the states to 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. 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 proposes to amend 42 CFR chapter IV as set forth below:

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

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

Authority: Sections 1102, 1106, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh).

§ 423.4 [Amended]

■ 2. In § 423.4, amend paragraph (4) in 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 continues to read as follows:

Authority: Secs. 1102, 1871, 1894(f), and 1934(f) of the Social Security Act (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 at § 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 of the section.

■ b. Revising paragraph (b).

■ 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 and removing paragraph (a)(3).

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

■ c. Adding a new paragraph (b).

■ d. 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 6 months elapse between the date of initial submission of the application and the entity's response to the CMS request for additional information, the entity must update the application to provide the most current information and materials related to the application.

(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)(1) 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. The State administering agency forwards waiver requests to CMS along with any concerns or conditions regarding the waiver.

(2) Entities submitting an application to become a PACE organization may submit a waiver request as a document separate from the application or in conjunction with and at the same time as the application.

(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 is revised to read as follows:

§ 460.40 Violations for which CMS may impose sanctions.

(a) In addition to other remedies authorized by law, CMS may impose any of the sanctions specified in §§ 460.42 and 460.46, if CMS determines that a PACE organization commits any of the following violations:

(1) Fails substantially to provide to a participant medically necessary items and services that are covered PACE services, if the failure has adversely affected (or has a substantial likelihood of adversely affecting) the participant.

(2) Involuntarily disenrolls a participant in violation of § 460.164.

(3) Discriminates 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, functional, cognitive or psychosocial status or need for health care services.

(4) Engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment, except as permitted by § 460.150, by Medicare beneficiaries or Medicaid beneficiaries whose medical condition or history indicates a need for substantial future medical services or long term services and supports.

(5) Imposes charges on participants enrolled under Medicare or Medicaid for premiums in excess of the premiums permitted.

(6) Misrepresents or falsifies information that is furnished to—

(i) CMS or the State under this part; or

(ii) An individual or any other entity under this part.

(7) Prohibits or otherwise restricts a covered health care professional from advising a participant who is a patient of the professional about the participant's health and functional status, medical care, or treatment for the participant's condition or disease, regardless of whether the PACE program provides benefits for that care or treatment, if the professional is acting within his or her lawful scope of practice.

(8) Operates a physician incentive plan that does not meet the requirements of section 1876(i)(8) of the Act.

(9) Employs or contracts with any individual who is excluded from participation in Medicare or Medicaid under section 1128 or section 1128A of the Act (or with any entity that employs or contracts with that individual) for the provision of health care, utilization review, medical social work, or administrative services.

(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 by:

■ a. Adding a note to paragraph (a).

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

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

■ d. Removing the reference ''§ 460.40(f)(1)'' in paragraph (a)(3) and adding in its place the reference ''§ 460.40(a)(6)(i)''.

The addition reads as follows:

§ 460.46 Civil money penalties.

(a) * * *

Note to paragraph (a). These amounts will be adjusted in accordance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act) (Sec. 701 of Public Law 114–74) and updated amounts will be published in accordance with any amendments to 42 CFR 1003.102.

* * * * *

■ 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 a 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 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.

(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) and adding paragraph (a)(8) to read as follows:

§ 460.62 Governing body.

(a) * * *

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

(8) Adopt and implement effective compliance oversight as described in § 460.63.

* * * * *

■ 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's program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance oversight program must, at a minimum, include the following core requirements:

(a) Establishment and implementation of an effective system for routine monitoring and identification of compliance risks. The system should include internal monitoring and audits and, as appropriate, external audits, to evaluate the PACE organization, including contractors, compliance with CMS requirements and the overall effectiveness of the compliance oversight program.

(b) 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.

(1) 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.

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

(3) 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 and (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 and 460.71 [Amended]

■ 19. Section 460.66 is amended by:

■ a. Redesignating paragraphs (b) and (c) as § 460.71(c) and (d), respectively.

■ b. Removing the paragraph (a) designation from § 460.66.

■ 20. Section 460.68 is amended by:

■ a. In paragraph (a)(2), removing the word ''or'' after the semicolon.

■ b. Revising paragraph (a)(3).

■ 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 by:

■ a. Revising paragraph (b)(1)(iii).

■ b. Adding paragraph (d)(6) introductory text.

■ c. Redesignating paragraphs (d)(5)(vi) through (ix) as paragraphs (d)(6)(i) through (iv).

■ d. Revising newly redesignated paragraphs (d)(6)(i), (ii), and (iii).

■ e. In paragraph (e), removing the term ''PACE Center services'' and adding in its place everywhere it appears the term ''PACE center services''.

■ f. In paragraph (e)(2), removing the reference ''§ 460.98(d)'' and adding in its place the reference ''§ 460.98(c)''.

The revisions and additions 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) 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).

* * * * *

■ 23. Section 460.82 is amended by revising paragraphs (c)(1), (e) introductory text, (e)(3), (e)(4), and (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 individuals other than the employees of the PACE organization.

(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.

§ 460.98 [Amended]

■ 24. Section 460.98 is amended by:

■ a. In the heading for paragraph (d), removing the term ''PACE Center'' and adding in its place the term ''PACE center''.

■ b. In paragraph (d)(3), removing the term ''Pace center'' and adding in its place the term ''PACE center''.

§ 460.100 [Amended]

■ 25. In § 460.100, amend paragraph (e)(3)(i) by removing the term ''POs'' and adding in its place the term ''PACE organizations'' and 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), (c)(2) introductory text, and (d)(3).

■ b. Redesignating paragraph (e) as paragraph (f).

■ c. Adding a new paragraph (e).

The revisions and addition 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:

* * * * *

(d) * * *

(3) The members of the interdisciplinary team, with the exception of the community-based physician in paragraph (c)(1)(ii) of this section, must serve primarily PACE participants.

(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 revising paragraphs (a)(1), (a)(2) introductory text, (a)(2)(i), (a)(3), (a)(4) introductory text, (b), (c), (d) introductory text, (d)(1), and (d)(2) introductory text to 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 members of the interdisciplinary team listed in paragraph (c) of this section must conduct an in-person reassessment.

* * * * *

■ 28. Section 460.106 is amended by revising paragraph (a) and 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).

■ 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. In § 460.120, amend paragraph (f) by removing the term ''quality assessment and performance improvement'' and adding in its place the term ''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. In § 460.134, amend 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. Removing the term ''quality assessment and performance improvement'' and adding in its place everywhere it appears the term ''quality improvement''.

■ b. Removing the term ''Quality assessment and performance improvement'' and adding in its place everywhere it appears the term ''Quality improvement''.

§ 460.138 [Amended]

■ 38. In § 460.138, amend paragraph (b) by removing the term ''quality assessment and performance improvement'' and adding in its place the term ''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:
■ a. Revising paragraph (a)(2).
■ b. Removing paragraph (a)(4).
The revision reads 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 by:
■ a. Redesignating paragraphs (a) through (e) as paragraphs (b) through (f), respectively.
■ b. Adding a new paragraph (a).
■ c. Revising newly redesignated paragraph (b)(1).
■ d. Further redesignating newly redesignated paragraphs (b)(2) through (6) as paragraphs (b)(4) through (8), respectively.
■ e. Adding new paragraphs (b)(2) and (3).
■ f. In newly designated paragraph (b)(4), removing the reference ''paragraph (b)'' and adding in its place the reference ''paragraph (c)''.
■ g. 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 spenddown liability or any amount due under the post-eligibility treatment of income process, as permitted under §§ 460.182 and 460.184.

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

* * * * *

(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. In § 460.172, amend 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:
■ a. Revising paragraph (b) introductory text.
■ b. Redesignating paragraphs (b)(3) and (4) as paragraphs (b)(4) and (5).
■ c. Adding a new paragraph (b)(3).
The revision and addition 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:

* * *

(3) Is sufficient and consistent with efficiency, economy and quality of care.

* * * * *

■ 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).
■ c. Adding a new paragraph (b)(2).
The revisions 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 SAA 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: July 15, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: July 19, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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