



National
PACE
Association

October 12, 2016

Andrew Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS—4168—P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850
<http://www.regulations.gov>

RE: CMS-4168-P—Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE)

Dear Acting Administrator Slavitt:

With the full support of our Board of Directors and on behalf of our membership which includes all 121 PACE organizations operating in 31 states, the National PACE Association (NPA) is pleased to submit comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule for Programs of All-Inclusive Care for the Elderly (PACE) published in the Federal Register on August 16, 2016.

NPA was founded in 1994 to perform a variety of activities critical to the success of the PACE model including policy analysis and advocacy, education, quality improvement, data analysis and research. We continue these activities today in support of a membership that has grown to 168 organizations, inclusive of 121 operating PACE organizations as well as a range of provider entities and others who are either pursuing or supportive of PACE development. These entities include nine state PACE associations who coordinate activities at the state level. NPA values its longstanding and strong working relationships with CMS and State Administering Agencies (SAAs) which are PACE organizations' partners in PACE development and implementation. We look forward to working with CMS and the SAAs to implement the changes to PACE requirements after the final rule is released.

I. GENERAL COMMENTS

NPA commends CMS for the thorough and thoughtful consideration that has gone into the development of the proposed rule. This consideration is evident in the proposed rule's approach to providing flexibility in how PACE operates while maintaining the high standard of care and critical delivery system qualities of the program. Accordingly, our comments are substantially in support of CMS' proposed

changes to current PACE requirements. Where we propose an alternative approach, NPA has considered how the regulation can be optimized to balance the following goals:

- Provide flexibility in PACE operations that supports efficiency and growth, to enhance value to PACE participants and expand access to the program;
- Promote participant-centered services, guided by the needs and preferences of the PACE participant;
- Preserve the provider-based attributes of the PACE program that establish its direct care relationship with its participants, address gaps in the availability of care generally and in geriatric-competent care specifically, and enhance the participant's access to an integrated delivery system.

With these tenets in mind, we have given considerable thought and attention to the role of the PACE interdisciplinary team (IDT) as it relates to the role of the PACE center. We believe a balance that supports growth while maintaining the quality and essential features of the PACE model can be found through clarity on the critical role of the PACE IDT and by focusing on participant-centered care. The PACE IDT is distinguished by its scope, its direct care relationship with participants, and its collaborative approach to assessment, care planning and delivery of care.

We believe these features of the PACE IDT are central to the PACE model's effectiveness and we are confident that they will be retained in the context of greater flexibility. Further, we believe that adherence to the principle of participant-centered care can guide the more flexible use of care settings. We appreciate the proposed rule's movement in the direction of greater operational flexibility and our intent is for PACE organizations to implement this flexibility in ways that allow for them to maintain the effectiveness of PACE IDTs and be participant-centered in the development and implementation of participants' care plans.

In addition to flexibility, PACE organizations rely on CMS' administrative and oversight practices to support their efficient and effective growth and operations. We have approached our comments on these provisions of the proposed rule by recognizing the roles of PACE organizations as both a health plan and a provider. These roles require that the systems, processes and procedures applied to PACE recognize its distinctness from the Medicare Advantage (MA) program. While we value the increasing clarity and systematic processes CMS has moved towards for PACE, fashioning these processes on systems developed for the MA program does not always address and may be inconsistent with the provider role of PACE organizations, a role that is not shared by MA plans.

An example of this is that MA plans have annual enrollment periods each year and, as a result, many CMS functions are tied to this yearly cycle. However, as providers, PACE organizations are not on a predetermined annual, or even quarterly, schedule with regard to when they may need to expand their capacity to deliver services. In our comment, we identify situations in which the application of MA or Part D requirements to PACE are problematic and require consideration of an alternative approach.

The comments contained in Parts II and III below present NPA's response to CMS' proposed changes to the current PACE regulation. Our comments are separated into two categories: (1) major concerns which we believe are most important to the overall success and growth of the PACE model; and (2)

additional comments which, while significant, have less impact. Within each broad category, comments are presented in numerical order, not in order of importance.

II. MAJOR CONCERNS REGARDING SPECIFIC PROVISIONS

§460.10: Purpose and §460.12: Application requirements.

NPA agrees with CMS' proposed changes to expand the current regulation to specify requirements for both: 1) initial applications submitted by entities seeking to be PACE organizations, and 2) applications submitted by PACE organizations seeking to expand existing geographic service areas. We ask, however, that, consistent with current practice, CMS specify in regulation that an application to expand a PACE organization's service area shall not require information that was approved previously by CMS in connection with the initial PACE application and which is not impacted by expansion of the service area. More significantly, we ask CMS to reconsider the requirement for a PACE organization to submit an application in order to add a new PACE center within an existing service area.

NPA believes expansion applications should not be required of PACE organizations seeking to open a new PACE center within an existing service area. This situation involves only experienced PACE organizations that have demonstrated their ability to comply with PACE requirements. Furthermore, because the addition of a PACE center within an existing service area adds capacity and can only enhance beneficiaries' access to PACE center services, CMS need not be concerned that access to care for the eligible population will be negatively impacted.

As an alternative to requiring an expansion application, we recommend that a PACE organization be allowed to open a new PACE center within an existing service area after providing CMS with appropriate notice. Such notice would be given a minimum of 60 days in advance of opening the PACE center and include the center's location, an assurance from the SAA of its support for the new center and willingness to amend the PACE organization's program agreement, and an attestation of financial solvency with supporting documentation as evidence of the program's financial capacity. Subsequently, prior to the new PACE center's opening, the PACE organization would provide CMS with the completed state readiness review confirming that the center meets all on-site review criteria. Any revised marketing materials would be submitted to CMS for review as is the case for any marketing materials undergoing revision.

Such a notification process would provide CMS and the SAA with information that is comparable to what is currently required of PACE organizations seeking to open a new center. The advantage is that the notification process would recognize the capabilities of operating PACE organizations and provide more flexibility with regard to when the new PACE center opens. The current application process requires the PACE organization to wait as long as 45 days after submission of the state readiness review to open a new center. It would be far preferable if the PACE center could open immediately following CMS' receipt of the completed state readiness review. This would expedite expanded access to PACE center services and relieve the PACE organization from incurring staffing and facility costs associated with the center prior to opening. Further, NPA requests that a PACE organization seeking to open a new PACE center

within its current service area would be able to submit such notification at any time, rather than be limited to quarterly submission windows as is the case with applications.

Consistent with the recommendation above, in situations where a PACE organization is moving an existing PACE center from one location to another and relocating an existing IDT(s), NPA maintains that completion of a notification process should be sufficient. Further, we ask that CMS require a limited state readiness review referring only to those elements of the readiness review that are impacted by a change of location. For example, in situations where an existing PACE center is moving to a new location, it would not be necessary to review program policies and procedures unless they require updating.

With respect to CMS' proposal to codify its current practice of requiring a PACE organization to have successfully completed its first trial period audit and, if applicable, implemented an acceptable corrective action plan before CMS and the State will allow a service area expansion or PACE center expansion, NPA concurs with the following modification. We request an exception of this requirement in cases where the PACE organization is relocating its PACE center to a new location which may be necessary due to unforeseen circumstances or to assure adequate access if program growth exceeds enrollment projections. In addition, because the timing of the first trial period audit impacts the ability of a PACE organization to grow, we respectfully request that CMS and the SAA commit to conducting trial period audits in a timely manner, with an expectation that the first year audit be completed not later than 15 months after the opening of the PACE program.

On pp. 21-22 of this comment letter, NPA is asking CMS to modify the PACE regulation to allow for a prospective PACE organization to enter into a two-way agreement with CMS to provide services to Medicare beneficiaries in those states that do not establish PACE as a State option under Medicaid. In these situations, NPA recommends that the PACE organization be required to submit the provider application with a statement by the State regarding which, if any, of the state functions the State is willing to perform, e.g., site readiness review, nursing home level of care determination, etc.

§460.20: Notice of CMS determination.

In general, NPA concurs with CMS' proposed changes to §460.20 to clarify the process for CMS' review of PACE organization applications and the timelines for requesting additional information and notifying applicants of its determination to either approve or deny the application. We are, however, concerned about CMS' proposal to require applicants to update their applications if more than six months elapse between the date of initial submission of the application and the entity's response to the CMS request for additional information. Is CMS proposing to require the applicant to withdraw its application and resubmit an entirely new application, or will there be less burdensome and more timely ways to update the existing application through submission of additional information? NPA strongly recommends the latter and that the submission of additional information not be subject to quarterly submission timeframes.

Delays in responding to CMS' request for additional information are often related to delays in completion of construction or licensing of the PACE center, or delays in scheduling the state readiness review. If applicants are required to restart the application process, the consequence is that the PACE center may be ready many months in advance of final approval of the application and participants' enrollment in the program. In addition to allowing applicants to update existing applications if time elapses, rather than resubmit new applications, NPA also requests that CMS modify the proposed requirement in §460.20(c)(2) to allow for 12, rather than six, months to elapse between the date of initial submission of the application and the entity's response to the request for additional information before the entity is required to update its application. This timeframe more appropriately recognizes the challenges facing PACE organizations to coordinate PACE center development with the application process without unduly compromising the timeliness of the information included in the application. We request that CMS be limited to requiring an entirely new application only in those situations in which an applicant is not demonstrating progress toward establishment of a new PACE organization or expansion into a new service area after one year.

In the preamble to the proposed rule, CMS states that it does not believe it is necessary to allow "deemed approval" for expansion applications as it has not done so in the past. We request that CMS reconsider this position and allow "deemed approval" of applications from PACE organizations seeking to expand a service area, with or without a new PACE center. Although CMS has always acted on expansion applications within the applicable timeframes, we see no reason to preclude deemed approval if CMS is unable to act on an expansion application in a timely manner for some reason.

§460.40: Violations for which CMS may impose sanctions.

While NPA appreciates that by expanding the causes for which CMS may impose sanctions and civil money penalties (CMPs) there would be alternatives to program termination for more serious violations, NPA is concerned about the potential effect of program sanctions and sizable CMPs imposed on PACE organizations. Decisions to impose sanctions and CMPs should take into account whether they essentially equate to program termination on the practical level. Excessively high CMPs could force closure of a PACE program for violations that do not rise to the level of those that would warrant termination under §460.50. We ask that CMS be extremely cautious and perform a thorough risk benefit analysis of the magnitude of CMPs for which they are granted discretion under the statute. Enforcement agencies must always weigh the detriment to the PACE program and associated loss of services for PACE enrollees against the deterrent effect of the CMP.

Related to enforcement actions, NPA would like to express appreciation for CMS' efforts to improve the consistency of audits across regions. We encourage CMS' continued efforts to hold PACE organizations to a consistent level of performance that is well understood by both PACE organizations and auditors. This becomes extremely important in the context of discussions of CMPs and sanctions.

§460.60: PACE organizational structure.

In response to removal of the requirement that PACE organizations be not-for-profit entities, NPA appreciates the potential for growth that for-profit sponsorship affords PACE. We encourage CMS to ensure that the performance of both not-for-profit and for-profit PACE organizations are held to uniform standards concerning the expectations of PACE organizations and related quality standards.

CMS proposes to require PACE organizations planning a change of ownership to comply with a 60-day advance notification requirement and requirements in 42 CFR part 422, subpart L (Effect of Change of Ownership or Leasing of Facilities During Term of Contract). Referring to subpart L, a change of ownership (as proposed to be applied to PACE organizations) is defined as: 1) the removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law; 2) an asset transfer, meaning transfer of title and property to another party; or 3) the merger of the PACE organization's corporation into another corporation or the consolidation of the PACE organization with one or more corporations, resulting in a new corporate body. (Transfer of corporate stocks or the merger of another corporation into the PACE organization's corporation, with the PACE organization surviving, does not ordinarily constitute a change of ownership.) Our primary concern is that this definition may encompass, perhaps unintentionally, situations in which a PACE organization's sponsoring entity undergoes a restructuring which has no impact on the PACE organization itself. We would not want these situations to result in a PACE organization having to provide advance notice and comply with requirements in subpart L.

In addition, NPA would like to comment on CMS' requirement for completion of a PACE provider application in situations when a change of ownership involves an acquiring entity that is not already a PACE organization. NPA has two comments in this regard:

1) NPA asks CMS to limit the requirement for an acquiring entity to complete a PACE application to those entities that have no experience with PACE program operations. We would not want the requirement for a provider application to apply in situations where the acquiring entity has experience with PACE although that experience might have occurred under a different corporate structure, for example, in a situation where a corporate partner pulls out and the PACE organization is left to a sole owner. We would not want the sole owner to be required to complete the PACE application process to qualify in its own right.

2) While we share CMS' concern that PACE organizations meet all necessary qualifications, we are concerned that a requirement to complete a PACE application under the usual PACE application process will result in a 6-9 months' long process to complete a change of ownership. This is of particular concern when the PACE organization seeking a change of ownership is experiencing serious difficulties, financial or otherwise, that may be addressed by the change of ownership. We are concerned that a lengthy application process may make it impossible to prevent the termination of a potentially viable PACE organization.

This result would lead to the disenrollment of PACE participants and significant disruption to the care delivery system for these vulnerable individuals. In these situations, we ask CMS to consider an alternative process, e.g., an expedited application process that is not subject to the quarterly submission windows or review periods in place for routine applications, or a provisional change of ownership that would allow the PACE program to continue operations while the prospective new owner completes the application process.

§460.63 (New): Compliance oversight requirements.

NPA recognizes the importance of PACE organizations' vigilance with respect to ongoing adherence to all PACE requirements and implementation of precautions to prevent fraud, waste and abuse and concurs with CMS' proposal for compliance oversight requirements consistent with the following comments.

CMS is proposing to eliminate the requirement for PACE organizations that have completed the trial period to have an on-site audit at least every two years. As a result, CMS will be reducing the number of audits by utilizing risk assessment to select those PACE organizations that will be audited each year. If CMS' proposal is finalized, it estimates the number of audits conducted annually will drop by half. At the same time, CMS proposes to expand considerably the compliance oversight requirements of PACE organizations. In general, we welcome this tradeoff and the opportunity for PACE organizations to focus their resources on self-assessment and internal compliance efforts.

In monitoring PACE organizations' compliance with the proposed expanded compliance oversight requirements, we request that CMS take into account significant differences between PACE organizations, and MA organizations/Part D plans (PDPs) in terms of program structure, size, staffing and available resources. PACE organizations are substantially smaller and, in contrast to insurer-based health plans, are fundamentally provider entities that, in addition, implement health plan functions. While still holding PACE organizations accountable, it is essential that CMS' evaluation of compliance with this requirement take into account these distinctions and how they impact PACE organizations' assessments of risk and vulnerability.

It is important that CMS not expect much smaller PACE organizations to implement this requirement in the same way as large MA and Part D plans. Precedence for this approach can be found in compliance program guidance issued by the Office of the Inspector General to individual and small group physician practices. See F.R. notice dated 10/5/2000 (Vol. 65, No. 194, pp. 59434-59452). Further, it is extremely important that CMS oversee this requirement consistently across regions. PACE organizations have reported considerable variation across regions in how they are audited and monitored. We appreciate CMS' ongoing efforts to achieve greater consistency and hope such efforts will extend to monitoring of PACE organizations' compliance oversight programs.

NPA does, however, disagree with CMS' estimates of the costs to PACE organizations of implementing this requirement, in particular the estimated annual \$11,888 cost for updating compliance oversight materials and for routine identification of risks. We anticipate that implementation of this requirement will require a considerable increase in staffing for the compliance functions needed to implement these

requirements, at a considerably higher cost. Depending on the structure of a PACE organization, we want to confirm that the required compliance position may reside within the PACE organization itself or within its parent.

We request that PACE organizations be given adequate time to fully comply with the proposed expanded compliance oversight requirements. Although PACE organizations implement compliance oversight consistent with current requirements under Part D and the Deficit Reduction Act (DRA), it will take time to modify current compliance oversight activities consistent with proposed new requirements. We request that PACE organizations have a minimum of 12 months following publication of the final PACE rule to implement compliance oversight programs consistent with requirements in the proposed rule. NPA expects to assist its members in this regard by undertaking efforts to develop policies and procedures that its members can adopt either in whole or in part.

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

NPA appreciates CMS' proposed change to §460.64(a)(3) which would allow PACE organizations to hire individuals who do not have one year of experience with a frail or elderly population by providing them with necessary training, either directly or through a training entity. This change provides PACE organizations greater flexibility to hire staff who have both the necessary skills and other important attributes, e.g., needed language and cultural competencies, but who, at the time of hire, lack specific experience with the PACE population. We are confident that PACE organizations can address this lack of experience with training and expect this change will expand PACE organizations' access to qualified drivers, home health aides, activity staff and others.

§460.70: Contracted services.

While NPA concurs with the specific changes that CMS is proposing to make to §460.70, we do have a concern related to the requirement in §460.70(a) that, "The PACE organization must have a written contract with each outside organization, agency, or individual that furnishes administrative or care-related services not furnished directly by the PACE organization except for emergency services as described in §460.100." More specifically, although PACE organizations should strive to have written contracts with each outside organization, agency, or individual that furnishes care to PACE participants, there are situations in which PACE organizations should have the ability to use providers or suppliers with which they do not have a contract in order to most effectively meet participants' needs or preferences.

For example, a PACE participant may need care from a particular medical specialist who is not willing to contract with a PACE organization, or a participant or his or her family may prefer to use a noncontract hospital. To allow PACE organizations to accommodate these and other similar situations, NPA requests that CMS modify §460.70(a) to require that PACE organizations have contracts sufficient to provide the full range of covered services acknowledging that use of noncontract providers may be necessary in some cases. In these situations, requirements in §460.68, §460.70(b)(1) and §460.70(d)(5)(i)-(iii) would

apply. To NPA's understanding, this recommendation is consistent with requirements of Medicare Advantage organizations for which use of noncontract providers is recognized in §422.214.

Request for comment on whether contracted services authorized by the PACE organization or services operated directly by the PACE organization should comply with the Home and Community-Based Settings (HCBS) regulation

NPA appreciates the opportunity to respond to CMS' request for comment on the applicability of the Home and Community-Based Settings (HCBS) regulation in PACE. In general, we believe that the PACE model of care is well-defined and consistent with the objectives of the HCBS rule to ensure that care is patient-centered and affords individuals choice in where, how and from whom care is provided as evidenced by:

- PACE organizations' primary objective is to enable PACE participants to maximize function and independence in the community as an alternative to permanent nursing home placement.
- PACE organizations are responsible for the development and implementation of participant-centered care plans that address each participant's individual care needs, preferences and goals. As part of the PACE assessment and care planning process, each participant and, as appropriate, his or her designated representative(s) share their preferences and goals for care. These preferences and goals become the basis for the participant's individualized care plan.
- Enrollment in PACE is voluntary and participants may voluntarily disenroll at any time in order to access alternative Medicare and Medicaid programs (§460.162).
- Individuals who enroll in PACE go through an intensive intake process during which the program is explained in detail, including how and where services are accessed. It is explained to prospective PACE participants that the PACE center is the location where many services are provided. Although PACE center attendance is not required for all participants, prior to deciding to enroll in PACE, individuals are knowledgeable about the characteristics of the PACE center. Similarly, PACE organizations that provide services, either directly or under contracts, in alternative care settings, e.g., adult day care centers, senior centers, and activity areas in residential communities where PACE participants reside, would also inform prospective participants of these care settings.
- PACE participants' rights under §460.112 include the rights to: 1) a choice of health care providers within the PACE organization's network; 2) participate fully in all decisions related to his or her treatment including the right to designate a representative, if necessary; and 3) be treated with dignity and respect, be afforded privacy and confidentiality in all aspects of care, and be provided humane care; to be free from harm, including physical or mental abuse, ..., and any physical or chemical restraint. These rights are consistent with individuals' rights under the HCBS rule.

Although PACE objectives and many specific PACE requirements are consistent with the requirements of the HCBS rule, we are concerned that a strict application of HCBS requirements may prevent PACE organizations from providing care in the PACE center, a setting defined in the PACE regulation where PACE participants may access primary care, including physician and nursing services; social services; restorative therapies, including physical therapy and occupational therapy; personal care and supportive services; nutritional counseling; and meals. A large proportion of PACE participants access services at

the PACE center although the frequency and combination of services is determined in response to each individual's needs and preferences.

Approximately half of PACE participants nationally have a diagnosis of dementia. The majority of these individuals need supervision to varying degrees, and a significant proportion cannot be left alone. While family members or paid caregivers may be available at night, it is often necessary for participants with dementia to attend the PACE center or an alternative care setting to ensure their safety.

Therefore, we oppose applying the HCBS rule to PACE for two reasons. First, the consistency that exists between the HCBS and PACE rules would make imposing the HCBS rule on PACE organizations duplicative. Second, the strict application of the HCBS rule may impact PACE organizations' ability to provide care to PACE participants in ways that have been demonstrated to be successful at delaying or preventing nursing home placement. We do not believe it is in the best interest of current and future PACE participants to preclude them from receiving services in the PACE center or alternative care settings.

Finally, adherence to the principle of participant directed care requires that the right of individuals to choose to participate in activities at the PACE center or alternative care settings must be protected to the same degree as their right not to choose to participate in those activities or to participate in activities in other community settings.

§460.82: Marketing.

NPA shares CMS' objective of ensuring that potential PACE participants receive accurate information about PACE. However, NPA is very concerned about the proposed change to §460.82(e)(4) prohibiting marketing by any individuals other than the employees of the PACE organization and its potential to limit PACE organizations' ability to educate potential PACE participants, their families and referral sources about the PACE program. NPA believes that a prohibition on marketing by any individuals other than the employees of the PACE organization is too broad. We recommend retaining the existing §460.82(e)(4) which prohibits PACE organizations from contracting outreach efforts to individuals or organizations whose sole responsibility involves direct contact with the elderly to solicit enrollment. We believe the current regulatory requirement provides sufficient protection to potential PACE participants while affording PACE organizations flexibility with regard to how information about the program can be disseminated.

By referring to "marketing" instead of "outreach," the proposed rule could be interpreted very broadly. Like many health care organizations, PACE organizations use outside experts to market their services, including advertising agencies, television and radio stations, newspapers, and persons with expertise in marketing over the internet and social media. It is crucial that PACE organizations retain the ability to avail themselves of these marketing resources in order to remain competitive and to ensure that potential enrollees have access to information about PACE.

In addition, states are playing an increasingly important role in educating Medicaid beneficiaries about Medicaid managed long term services and supports options. We are concerned about how CMS'

proposed restriction would impact states' efforts to share information about PACE, particularly in those states that contract with entities to provide options counseling to Medicaid beneficiaries. We would not want CMS requirements to prevent states from including PACE in efforts to inform beneficiaries of their LTSS options.

Because enrollment in PACE requires the intensive intake process described in §460.152 which involves PACE organization staff directly, enrollment in a PACE organization differs substantially from enrollment in a MA plan which can be completed by a contracted agent or broker. The PACE enrollment process and its requirements ensure that potential PACE participants are fully informed by PACE employees about the way in which PACE programs provide services and participants' responsibilities prior to enrollment. If CMS remains concerned about the accuracy of information potential participants receive prior to engaging directly with the PACE program, rather than prohibit the use of contracted entities to engage in marketing activities and generate referrals to PACE organizations, we recommend language reinforcing the PACE organization's responsibility to assure prospective participants receive accurate information, regardless of whether it is provided by employees, or contracted entities or individuals.

§460.98: Service delivery and §460.6: Definitions.

NPA appreciates CMS' request for comments on potential changes to PACE center requirements and ways to revise current regulatory requirements to allow greater flexibility with regard to settings in which PACE 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.

NPA recognizes the PACE center's role as an important service delivery setting for PACE participants, but we believe the current regulation is overly restrictive with regard to participants' attendance at a PACE center and the assignment of participants to IDTs that are, by definition, attached to the PACE center. NPA believes that the PACE IDT is the most distinguishing core feature of the PACE model and the mechanism by which all Medicare- and Medicaid-covered benefits and services are integrated. Responsible for assessment, care planning, and direct service delivery, the PACE IDT establishes a relationship with PACE participants on a continuous and ongoing basis. Currently, the PACE center houses the PACE IDT, but it is not essential that this be the case. We believe the PACE IDT can be located in other settings and across a range of settings as long as processes are in place to assure effective communication among PACE IDT members and additional care providers.

Further, while the PACE center may be the preferred setting of care for many PACE participants, this is not always the case. It is already true that a subset of PACE participants rarely, if ever, attend the PACE center. Although all PACE participants have access to PACE center services, a proportion prefer to receive services at home or in alternative care settings (ACSS) such as adult day care centers, senior centers, activity areas in residential communities, etc. In recognition of this, NPA believes that the PACE regulation should allow for use of ACSS explicitly. Such a change would simultaneously provide PACE organizations more flexibility in responding to participants' needs and preferences, and promote PACE growth and expansion in ways that are not constrained by PACE organizations' ability to construct new PACE centers.

Moving forward, NPA recommends that CMS modify PACE requirements consistent with the following principles:

- All PACE participants must be assigned to a PACE IDT, but the IDT does not have to be assigned to a PACE center.
- All PACE organizations must have at least one PACE center furnishing, at a minimum, the services listed in §460.98(c).
- All PACE participants must have access to a PACE center with some specific allowances for PACE organizations in rural areas.
- Although access to the PACE center should be available to all PACE participants, assignment to a PACE center should not be required for PACE participants. Rather, all PACE participants should be assigned to an IDT which may or may not be assigned to a PACE center.
- PACE participants may receive services in settings other than the PACE center, the home and inpatient facilities consistent with their individualized care plans. The settings in which a participant receives care should reflect participants' needs and preferences, i.e., the determination as to the most appropriate setting should be participant centered. NPA strongly recommends that CMS apply this criterion rather than restricting access to ACSs to participants "that may otherwise undergo hardship and or extraordinary circumstance to attend the PACE center." (CMS memorandum dated 6/30/2016 titled, "Clarification on the Requirements for Alternative Care Settings in the PACE Program.")
- Assessing whether a PACE organization has sufficient PACE center capacity should take into consideration the availability of and PACE participants' use of ACSs.

We believe it is important to allow greater flexibility with regard to the settings in which PACE participants receive care and participants' access to care in alternative settings. Therefore, we recommend that clarification of how PACE organizations may utilize ACSs should not be delayed until future rulemaking. We ask that CMS provide such clarification as part of the current rulemaking process or, at a minimum, through additional subregulatory guidance. Fundamentally, we ask CMS to affirm that PACE participants may access PACE services in ACSs based on their needs and preferences, without having to demonstrate undue hardship or extraordinary circumstance as indicated in CMS' 6/30/2016 memorandum to PACE organizations. The use of an ACS should be possible if it is the result of a participant-directed care planning process. The PACE IDT, fully taking into account the care needs and preferences of PACE participants and their caregivers, should have the flexibility to determine the best combination of PACE center, in-home and, if appropriate, other community-based setting services for each participant.

§460.102: Interdisciplinary team, §460.104: Participant assessment, and §460.106: Plan of care.

Expanded definition of primary care provider on IDT (§460.102(b)(1) and §460.102(c)). NPA strongly supports CMS' proposed changes to §460.102(b)(1) and §460.102(c) allowing for nurse practitioners, physician assistants, and community-based physicians, in addition to PACE physicians, to be primary care providers on the PACE IDT. Currently 73 or more than 50% of all PACE organizations use nurse practitioners as primary care providers (PCPs) on the PACE IDT under BIPA 903 waiver authority. These

waivers have demonstrated the effectiveness of nurse practitioners in this role. Although physician assistants have not, up to this point, been able to assume the role of primary care provider on the PACE IDT, there are a number of physician assistants practicing in PACE organizations. Given the opportunity, NPA is confident they will be effective members of the IDT.

With respect to community-based physicians, over 20 PACE organizations have waivers allowing them to use community-based physicians as primary care providers on their IDTs. All of these primary care provider arrangements have allowed for greater flexibility in the delivery of primary care to PACE participants, addressing the challenges PACE organizations face in hiring sufficient numbers of primary care providers, allowing for program growth, and enhancing efficiency without compromising quality. In the case of community-based physicians, their use has allowed PACE participants expanded choice of primary care providers beyond PACE staff, sometimes allowing them to retain an existing primary care physician when enrolling in PACE. Allowing PACE organizations to use nurse practitioners, physician assistants and community-based physicians as primary care providers on the PACE IDT without the need for waivers is an appropriate and necessary change to the existing regulation.

Consistent with CMS' objective of expanding the use of non-physician primary care providers, NPA recommends that CMS clarify that physician assistants and nurse practitioners in proposed §460.102(c)(1)(iii) and (iv) can provide services in the PACE center as well as other community-based settings including private practices as is the case with community-based physicians. Similarly, a modification to §460.98(c)(1) is needed to recognize that primary care services in the PACE center may be provided by a physician, nurse practitioner or physician assistant, along with nursing services.

To facilitate PACE organization's use of community-based PCPs (physicians, nurse practitioners and physician assistants) as primary care providers on the PACE IDT, NPA recommends that CMS allow for some flexibility in how they fulfill their IDT responsibilities. In particular, it is important that PACE organizations have some flexibility in determining how community-based PCPs participate in PACE IDT discussions to develop participants' care plans. Today, PACE organizations with waivers to use community-based physicians as primary care providers on the PACE IDT represent a range of approaches in how the community-based physician participates in team discussions, including directly and through a liaison. If implemented effectively, these alternative approaches to direct participation of the community-based PCP will not compromise the care planning process.

NPA believes the PACE regulation should allow for alternatives to direct participation in PACE IDT discussions as long as the approach ensures the community-based PCP participates actively in the care planning process. For example, if the community-based PCP participates in IDT discussions through a liaison, communications between the community-based PCP and the liaison in preparation for the liaison's contribution to the IDT should be interactive, consultative and substantive. Further, NPA believes the liaison should also be a primary care professional, and it should not be sufficient for the community-based PCP to only provide notes or other written information to the liaison. We encourage CMS to allow for community-based PCPs to participate in IDT discussions either in person or through alternative means consistent with what we have described here, but encourage specificity in subregulatory, rather than regulatory, language.

Allowing for individuals to fulfill two separate roles on the IDT (§460.102(b)). NPA concurs with CMS' proposal to allow one individual to fulfill a maximum of two separate roles on the PACE interdisciplinary team when the individual is qualified to fill each role and able to provide appropriate care to meet participants' needs. NPA appreciates the flexibility this will provide PACE organizations to configure their interdisciplinary teams efficiently without compromising participants' quality of care. We expect this flexibility will be particularly useful for newly operational and smaller PACE organizations, including those in rural areas. In its preamble to the proposed rule, CMS refers to IDT guidelines that will be published in HPMS following publication of the final rule. NPA would appreciate the opportunity to provide CMS comments on these guidelines in advance of their publication.

Elimination of "primarily serve" requirement (§460.102(d)(3)). NPA concurs with CMS' proposal to eliminate the "primarily serve" requirement for community-based physicians. Consistent with our comment on §460.102(b)(1) we would extend this to other community-based PCPs. Further, because the current "primarily serve" requirement is vague and leads to inconsistent interpretation, we believe the "primarily serve" requirement should be removed for all PACE IDT members. PACE organizations face many operational realities, e.g., the need to hire part-time staff consistent with staffing needs as program census increases, the need to access qualified staff who may not choose to devote themselves to the PACE organization on a full-time basis. Rather than regulating the proportion of time a PACE IDT member is devoted to PACE, we believe the focus should be on ensuring that his/her responsibilities on the IDT are fulfilled.

Composition and Role of PACE Interdisciplinary Team in Assessment and Care Planning (§460.102, §460.104 and §460.106). NPA appreciates CMS' request for comment on the possibility of deleting requirements in §460.102(b) related to composition of the PACE IDT. We believe it continues to be useful to retain the range of health professionals and functions identified in §460.102(b) that a PACE organization must be able to convene in order to perform the full range of its assessment and care planning functions. However, we recommend that the team members who are required for distinct types of assessments and care plans (see below) reflect the scope and intent of each type. NPA's approach calls for the composition of the IDT to vary over time and in response to the needs of individual PACE participants as we explain below.

PACE organizations perform the following distinct types of scheduled and unscheduled assessment and care planning functions:

- 1) Initially/Upon Enrollment
 - Initial Assessment
 - Initial Care Plan
- 2) Semiannually
 - Semiannual Reassessment
 - Semiannual Care Plan
- 3) Annually
 - Annual Reassessment
 - Annual Care Plan
- 4) Unscheduled (Due to Change in Status)
 - Unscheduled Reassessment

- Unscheduled Care Plan
- 5) Service Request
- Service Request Reassessment
 - Service Request Care Plan

The team members required for each type of assessment and care plan vary by the scope of the assessment and by the specific needs of each participant. To address the range of required team members needed, we recommend that CMS identify the following types of team compositions:

PACE Interdisciplinary Team (IDT): The PACE IDT is comprised of the full range of health professionals and functions that a PACE organization is able to convene in order to meet the needs of its PACE participants.

- (1) Primary care provider
- (2) Registered nurse
- (3) Master's level social worker (MSW)
- (4) Physical therapist
- (5) Occupational therapist
- (6) Recreational therapist or activity coordinator
- (7) Dietitian
- (8) PACE center manager
- (9) Home care coordinator
- (10) Personal care attendant or his or her representative
- (11) Driver or his or her representative

NPA concurs with CMS as noted above that an individual may represent as many as two of the above functions on the IDT.

The Core Assessment Team members (see immediately below) are drawn from the PACE IDT.

Core Assessment Team (CAT): The Core Assessment Team is comprised of the health professionals and functions that are required for all assessment and care planning functions:

- (1) Primary care provider
- (2) Registered nurse
- (3) MSW

With these two team definitions in mind, in the table below, NPA presents the required team compositions we recommend for each assessment and care planning function performed by a PACE organization.

NPA Required Team Composition Recommendations for Assessments and Care Planning

Type	NPA Recommended Assessment Team	NPA Recommended Care Planning Team
Initial/Upon Enrollment	CAT plus: PT, OT, RT/activity, dietitian, home care coordinator. The CAT may add other professionals as needed.	CAT plus: PT, OT, RT/activity, dietitian, home care coordinator. The CAT may add other professionals as needed.
Semiannual	CAT. The CAT may add assessments by other IDT members as needed.	CAT plus: Other IDT members who performed a semiannual reassessment and other IDT members who the CAT determines are actively and substantively involved in the participant's care.
Annual	CAT plus: PT or OT. The CAT may add assessments by other IDT members as needed.	CAT plus: PT or OT; other IDT members who performed an assessment; and other IDT members who the CAT determines are actively and substantively involved in the participant's care.
Unscheduled due to change in status	CAT plus: PT or OT. The CAT may add assessments by other IDT members as needed.	CAT plus: PT or OT; other IDT members who performed an assessment; and other IDT members who the CAT determines are actively and substantively involved in the participant's care.
Unscheduled due to service request	CAT determines which members of the IDT are related to the service request. The related IDT member(s) conduct the assessment(s) as needed.	CAT plus: members of the IDT who conducted an assessment related to the service request and other IDT members who the CAT determines are actively and substantively involved in the participant's care.

Initial Assessment and Care Plan

Similar to CMS' proposal, NPA is recommending that an interdisciplinary team composed of members qualified to fill the eight required assessment roles in §460.104(a)(2) (primary care, nursing, social work, OT, PT, recreational therapy/activities, dietitian and home care coordinator) and additional professionals as determined by the CAT complete an initial assessment and that these same individuals would be required to develop and approve the initial care plan for a PACE participant. NPA's recommendation differs from CMS' proposal in that: 1) the CAT, rather than the IDT, would determine if other professional disciplines need to perform assessments, and 2) it would no longer be required that the PACE center manager, the personal care attendant or his or her representative, and the driver or his or her representative would need to participate in the development of the initial care plan as is currently the case under §460.104(b).

Semiannual Reassessment and Care Plan

NPA's recommendations for semiannual reassessments differs somewhat from CMS' proposed rule. Consistent with CMS, NPA agrees that a semiannual reassessment should involve, at a minimum, the CAT. Further, we agree that it is not necessary for the recreational therapist/activity coordinator to perform a semiannual reassessment. If an RT/activity coordinator is involved in the participant's plan of care, he/she has regular interaction with the participant and would not rely on a scheduled reassessment in order to be aware of the participant's needs.

NPA's recommendation differs from CMS' proposal in regard to the requirements for other IDT members to undertake reassessments. While we believe it is appropriate to place the responsibility for identifying which additional IDT members are needed with the CAT, we believe that the criterion, "actively involved in the development or implementation of the participant's plan of care," is too broad for determining who is needed to perform a reassessment. We recommend leaving the determination of which IDT members should undertake reassessments up to the CAT without imposing specific criteria for the CAT to use in its determination. NPA believes this allows for more flexible use of IDT resources without compromising participant's quality of care. If all members of the IDT who are actively involved in the care plan are required to perform reassessments, it is likely that semiannual reassessments will involve, at a minimum, the RT, the PACE center manager and the home care coordinator as most PACE participants attend the PACE center and receive home care. For reasons expressed above, we do not believe that a reassessment is necessarily required by a RT who is likely involved in the implementation of the majority of participants' care plans. The same can be said for other IDT members, such as the PACE center manager or home care coordinator.

With respect to updating and approving the plan of care, NPA recommends that IDT members who perform reassessments as well as other IDT members that the CAT determines are actively and substantively involved in the participant's plan of care should be involved in care planning. This is in contrast to CMS' recommendation to involve all IDT members in updating the care plan consistent with 460.104(e)(2) and (3).

Annual Reassessment and Care Plan

NPA also recommends a different approach to annual reassessment requirements for PTs and OTs. We believe that it is important for all participants, regardless of whether a PT and/or OT is involved in a participant's plan of care, to be assessed at least once a year by a rehabilitation therapist, i.e., either a PT or an OT. Under CMS's recommendation, participants with a PT or OT actively involved in their plan of care would receive a reassessment; but those without this active involvement would not. As an alternative to CMS' approach, we recommend that either a PT or OT assess all participants at least annually with the need for reassessments from additional IDT members left to the discretion of the CAT. We believe this change more appropriately recognizes that participants' functional abilities may decline over time and the importance of rehabilitative therapy to maximizing function and independence for the population enrolled in PACE.

Again, care plans would be developed and approved by the IDT members who perform reassessments as well as other IDT members that the CAT determines are actively and substantively involved in the participant's plan of care.

Significant Change Reassessments and Care Plan

Similar to the annual reassessment and care plan, we recommend that participants who experience a significant change in health status should be assessed, at a minimum, by the CAT, and a PT or OT with the need for additional assessments determined by the CAT. Updates to the care plan following a change in health status would be developed and approved by the IDT members who perform assessments as well as other IDT members that the CAT determines are actively and substantively involved in the participant's plan of care.

Request for Service Reassessments and Care Plan

For reassessments precipitated by a participant's or caregiver's request for service, NPA recommends retaining a slight variation on the current requirement. Specifically, the participant's CAT should determine the IDT members needed to perform an assessment. We do not believe that all service requests should require an in-person reassessment by the PCP, RN, MSW and other IDT members determined to be actively involved in the development or implementation of the participant's plan of care. For example, a participant or caregiver may request an additional day's attendance at the PACE center or several additional hours of home care. These types of requests should not necessarily lead to a requirement for the PCP, RN and MSW to conduct a reassessment. Care plan updates in response to a request for service reassessment should be developed and approved by the CAT, those IDT members who performed assessments and other IDT members that the CAT determines are actively and substantively involved in the care plan.

Timeframe for completion of initial comprehensive assessments (§460.104(a) and §460.104(b)). In general, NPA concurs with CMS' proposal to require that initial comprehensive assessments be completed in time to allow the IDT to complete the plan of care within 30 days of enrollment. We do, however, believe it is necessary to recognize that there are situations in which the deadline cannot be met, e.g., when a participant is hospitalized or out of the service area during the initial 30 days of enrollment or refuses to complete the assessment and care planning process within 30 days of enrollment. Under these and other extenuating circumstances, NPA requests that CMS allow for the PACE organization to document the reasons the care plan was not completed within 30 days without being determined to be out of compliance. It is important to note that, even in these situations, the IDT would develop an interim care plan until a comprehensive care plan based on the initial comprehensive assessment findings is completed.

Consolidation of assessments into plan of care through team discussions (§460.104(b)). NPA concurs with CMS' proposal to require assessments be consolidated into a plan of care through "team discussions" rather than current "discussions in team meetings." We appreciate CMS' recognition of the need to allow for flexibility in methods of IDT communications and use of conference calls, video

conferencing, etc. This is particularly important in the context of CMS' proposal to allow community-based primary care physicians to be members of the IDT and NPA's recommendations to expand the provision of care in settings other than the PACE center.

Documentation of reasons certain services are not included in plan of care (new §460.104(b)(1)). NPA disagrees with CMS proposal to require the IDT to document in the participant's plan of care the reasons services "associated with the comprehensive assessment criteria" are not included in the plan of care. The plan of care should focus on the services that are being provided based on the needs assessments of IDT members and the preferences of the participant. If the participant requests a service that is not included in the care plan, he/she may file an appeal.

We have attached Exhibit 1 which suggests one approach to revising regulatory language consistent with NPA's recommendations on pp. 11-19 for changes to §460.102, 104 and 106. We recognize that our comments related to the IDT, assessment and care planning are extensive, and are hopeful that Exhibit 1 is helpful to CMS in understanding our intent.

§460.162: Voluntary disenrollment.

In regard to CMS' proposal to require that POs ensure their employees or contractors do not engage in any practice that would reasonably be expected to have the effect of steering or encouraging disenrollment of PACE participants due to a change in health status, NPA agrees completely with the objective of this requirement. It is the case, however, that PACE participants may voluntarily disenroll from the program without cause at any time and it is possible that a PACE participant may choose to disenroll in response to a change in health status. We would not want proposed §460.162(c) to place PACE organizations in jeopardy by holding them responsible for decisions made independently by PACE participants with respect to how they receive their care. PACE organizations also are concerned that an employee of a contract provider, e.g. nursing home, may suggest disenrollment to a resident, including new residents who may have recently experienced a change in health status. PACE organizations should have the opportunity to address such an issue before a sanction is imposed.

III. ADDITIONAL COMMENTS REGARDING SPECIFIC PROVISIONS

§460.3: Part D program requirements.

NPA concurs with CMS' proposal to add §460.3, "Part D Program Requirements," to state that PACE organizations offering qualified prescription drug coverage and meeting the definition of a Part D plan sponsor must abide by all applicable Part D program requirements in part 423. Moreover, we appreciate CMS' efforts to consolidate all requirements affecting PACE organizations in part 460.

To clarify further which Part D requirements are applicable to PACE organizations, we request that CMS explain in §460.3 that, consistent with 42 CFR Part 423.458(d), PACE organizations are waived of Part D program requirements to the extent that CMS determines that the provision duplicates, or is in conflict with, provisions otherwise applicable to PACE organizations under sections 1894 and 1934 of the Act, or as necessary in order to improve coordination of Part D with the benefits offered by PACE organizations. These waivers are crucial to PACE organizations' ability to implement Part D in a manner consistent with

PACE requirements and, most importantly, the needs of PACE participants. Further, we request that CMS specify in the new §460.3 the particular Part D requirements that are waived for PACE organizations, include a recognition that future waivers may be applied to all PACE organizations as needed to reflect future Part D regulations, and specify the process available to PACE organizations seeking additional waivers.

Consistent with specifying in §460.3 that PACE organizations must abide by all applicable Part D program requirements, we respectfully request the following:

- (1) Part D guidance issued through HPMS should specify whether or not it is applicable to PACE organizations and, if so, whether it applies to them in the same manner as it does to MA-PDs and PDPs. We would appreciate CMS' efforts in this regard and believe it would reduce some of the confusion among PACE organizations about the applicability of specific Part D requirements that CMS refers to in the preamble to the proposed rule.
- (2) CMS audits should take into consideration differences between PACE organizations, and MA-PDs and PDPs, both in terms of applicable Part D requirements, and program operations. More specifically, we request that the audit guides used to evaluate PACE organizations' compliance with Part D requirements specify those Part D requirements that are waived for PACE organizations. Further, we encourage CMS to work with auditors to understand the differences between PACE organizations, and MA-PDs and PDPs. For example, it is important that oversight of PACE organizations' compliance activities takes into account key differences between PACE organizations and Part D plans in terms of size and structure when evaluating PACE organizations' risk for fraud, waste and abuse.

In addition, in the context of our comment related to Part D and PACE, NPA would like to raise the issue of Part D premiums for Medicare-only PACE participants. As a result of the way in which the PACE Part D benefit is structured for Medicare-only beneficiaries enrolled in PACE, they are unable to access the Medicare Coverage Gap Discount program or the catastrophic component of the Part D benefit like Medicare enrollees in other Part D plans. Consequently, Part D premiums for Medicare-only PACE participants are very high, and NPA would like to ask CMS to work with us to explore ways of reducing their Part D costs.

§460.26: Submission and evaluation of waiver requests.

NPA seeks clarification of the process for submitting waiver requests in conjunction with the PACE application. §460.26(a)(1) indicates that a PACE organization or entity seeking to become a PACE organization must submit its waiver request through the SAA which then forwards it to CMS. §460.26(a)(2) indicates that entities submitting an application to become a PACE organization may submit a waiver request in conjunction with and at the same time as the application. Because the application is submitted by the applying entity and not the state, we seek clarification as to whether the PACE organization can submit a waiver request as part of its application.

§460.28: Notice of CMS determination on waiver requests.

NPA is concerned that, in cases in which CMS determines a waiver application is incomplete, there is no timeframe in which CMS must inform the waiver applicant of this determination. NPA recommends that CMS make a determination regarding the completeness of the waiver application within 30 days of receipt and inform the applicant accordingly. Further, we ask CMS to specify a “date of submission,” as is the case for applications in §460.20(e), to specify the date on which CMS receives the complete waiver request. Lastly, in consideration of the other regulatory changes that CMS is proposing, it is reasonable to expect that PACE organizations will submit fewer waiver requests, and we ask that CMS approve or deny waiver requests within 60, as opposed to 90, days of receipt of a complete waiver request.

§460.30 Program agreement requirement.

NPA concurs with CMS’ proposal to require that either the Medicaid capitation rate(s) or Medicaid payment rate methodology be included in the PACE program agreement. We agree with CMS that the change will both: 1) accommodate situations in which Medicaid payment rates vary based on factors such as frailty adjustments and performance incentive payments, and 2) be less administratively burdensome. With regard to states that opt to include their Medicaid payment rate methodology in the program agreement, we request that the methodology be described in sufficient detail in order to enhance the transparency of the Medicaid rate-setting process. In addition, we would like to take this opportunity to request that CMS work closely with SAAs to ensure that Medicaid rates are updated appropriately (generally annually but at a minimum once every 3 years).

In response to CMS’ request for input on other modifications they might make to the required content of the PACE program agreement, NPA has the following comments:

- It is our understanding that there is some inconsistency across PACE organizations’ program agreements in terms of their contents and the extent to which they are updated to reflect current rates, policies and procedures, etc. Once a final determination has been made regarding the content of the program agreement moving forward, we encourage CMS to engage SAAs and PACE organizations to ensure consistency and completeness. We would also appreciate a clearer understanding of what is required of PACE organizations relative to updating the program agreement, what the process is, etc.
- We encourage CMS to engage with its SAA partners to determine which components of the program agreement are necessary from the states’ perspective, and we would support efforts to remove detailed information that changes with some frequency, e.g., administrative contacts which are available in CMS’ Health Plan Management System. In general, we expect the program agreement would include high-level requirements as opposed to specific program policies and procedures. Again, we encourage CMS to consult with SAAs on this issue to avoid situations in which information important to states is inadvertently eliminated from the program agreement.

In addition, NPA recommends that CMS modify the PACE regulation to allow for a prospective PACE organization to enter into a two-way agreement with CMS to provide services to Medicare beneficiaries in those states that do not establish PACE as a State option under Medicaid. Currently 19 states have not

elected PACE as a voluntary state option. As a result, PACE is not available to any Medicare beneficiaries in these states regardless of their Medicaid status. NPA believes that Medicare beneficiaries who have the resources to pay privately for PACE should have the option to do so if a PACE organization is willing to establish itself in a state where PACE is not included in the Medicaid program. In a two-way agreement, the Medicaid rate(s) or Medicaid rate setting methodology would not be applicable and would be replaced by the methodology used to establish private-pay premiums for PACE. We recognize that this proposal would necessitate other changes to the regulations, such as the application process, the mechanisms by which CMS or its delegate would assume the role of the SAA, etc. NPA would be happy to discuss those changes with CMS further.

§460.34: Duration of PACE program agreement.

Section 460.34 currently reads, “An agreement is effective for a contract year, but may be extended for additional contract years in the absence of a notice by a party to terminate.” NPA recommends this language be modified as follows: “An agreement is effective for a contract year, but shall be extended for additional contract years in the absence of a notice by a party to terminate.”

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

NPA concurs with CMS’ proposal to eliminate the requirement for CMS to approve the position-specific competencies referenced in §460.64(a)(4). We believe this will provide PACE organizations greater flexibility to update their competency programs consistent with industry standards and program needs. Further, we appreciate the opportunity to reduce CMS’ burden in administering PACE.

§460.68: Program integrity.

NPA appreciates that PACE organizations will have greater discretion to hire individuals who have had prior convictions that do not pose a risk to the PACE program. We agree with CMS that there are circumstances in which certain convictions that took place many years ago should not universally disqualify an individual from consideration for employment. We trust that PACE organizations will exercise this discretion carefully. More specifically, the proposed change may be helpful in situations in which a participant would like to self-direct his or her care and has identified a caregiver who may have a prior conviction that meets the criteria in current §460.68(a)(3) but who would not pose a risk.

NPA concurs with CMS’ proposal to add two additional limitations on PACE organizations employing or contracting with individuals or organizations: (1) PACE organization must not employ or contract with individuals or organizations who have been found guilty of abusing, neglecting, or mistreating individuals by a court of law or who have had a finding entered into the state nurse aide registry concerning abuse, neglect, mistreatment of residents, or misappropriation of their property, and (2) PACE organization must not employ or contract with individuals or organizations who have been convicted of crimes listed in section 1128(a) of the Social Security Act.

In response to CMS' specific request for comment on whether hiring restrictions should be imposed on individuals with current restraining orders against them, we believe that such a requirement would be problematic. First, on a practical level, processes and data sources available to PACE organizations to determine if a restraining order is in effect may be unreliable. Second, our members have found that it may be difficult to evaluate the legitimacy of a restraining order. As a result, NPA opposes the imposition of additional requirements that would require PACE organizations to engage in activities to determine if potential employees have current restraining orders against them. We believe that current requirements for background checks are sufficient.

Further, our understanding is that such a requirement would impose a higher standard on PACE organizations than is required of nursing homes that provide care to a comparable population. If a PACE organization were to become aware of a restraining order against a potential hire, e.g., through the process of a background check or other means, we believe it should have discretion with regard to hiring consistent with the requirements for criminal convictions. As with the criminal convictions, our members believe that it is best to offer PACE organizations' discretion in evaluating the specifics of the restraining order and the position. As a result, at this time, we oppose the imposition of regulatory limitations on hiring individuals with current restraining orders against them.

§460.82: Marketing and §460.116: Explanation of rights.

NPA shares CMS' objective of making information readily accessible to current and prospective PACE participants. However, we propose two modifications to the proposed definition of "other principal languages in the community," that would apply in states that have not established a standard. Rather than defining principal languages of the community as those languages spoken in the home by at least 5 percent of the individuals in the PACE organization's service area, we recommend that, for purposes of PACE, principal languages be defined as those languages spoken in the home by at least 10 percent of individuals who are eligible for PACE in the PACE organization's service area. Because it may not be possible to identify those individuals likely to be eligible for nursing home care, at a minimum, we recommend that principal languages of the community be defined for those who are 55 years of age and older. We believe this modification will increase access to information for the population that needs and would benefit most from information about PACE.

In addition, we recommend a 10 percent threshold in consideration of the costs of producing marketing materials in many languages. Relative to MA plans which are subject to the 5% requirement, PACE organizations are typically much smaller and, therefore, the cost of producing materials in multiple languages is greater in comparison. We do not believe that increasing the threshold will compromise individuals' access to information. As a result of the nondiscrimination rule, notice of the availability of language assistance services is included as a tagline in the top 15 languages spoken by individuals with limited English proficiency in the state on all significant publications and significant communications. In addition, we believe this variance from the Medicare Advantage requirement is appropriate because PACE organizations rely more heavily on face-to-face communications for which language interpretation services are available.

In response to CMS' proposal to specify that all unsolicited means of direct contact are prohibited, including calling or emailing, NPA would like to confirm that this requirement would not prohibit a PACE organization from: 1) sending a mailing to a prospective participant or their caregiver, or 2) participating in an educational event where the PACE organization presents information on PACE in a community or residential setting.

In response to CMS' proposal to delete the requirement that a PACE organization must establish, implement, and maintain a documented marketing plan, NPA concurs that CMS has a variety of other ways to stay informed of a PACE organization's marketing activities.

§460.98: Service delivery.

Because the PACE IDT may include either a recreational therapist or activities coordinator, NPA recommends substituting the more general term, "Recreation and activity services" for "Recreational therapy" in §460.98(c)(6).

§460.102: Interdisciplinary team.

Although NPA is not requesting a change to the current requirement for Master's level social workers (MSW) on the interdisciplinary team in §460.102(b)(3), we are aware that PACE organizations have requested waivers of this requirement to address their unique circumstances. More specifically, a PACE organization may serve a large number of participants who do not speak English and have difficulty hiring sufficient numbers of Master's level social workers with the language skills to communicate with its participants. In these situations, PACE organizations may request a BIPA 903 waiver from CMS allowing them to utilize Bachelor's level social workers or individuals with relevant educational qualifications (e.g., masters' degree in counseling, marriage and family therapy, etc.) and experience on the IDT as long as they are supported by MSWs and meet competency requirements. Currently, to our understanding, CMS has approved such waivers for individual social workers and one organizational-wide waiver of this requirement. We request that CMS consider expanding its approval of organization-wide waivers of the MSW requirement for PACE organizations demonstrating the need for such waivers and assuring that appropriate safeguards are in place to assure quality care. Our objective in making this request is to reduce the administrative burden related to the submission and review of multiple waiver applications on the PACE organization, the State administering agency and CMS.

§460.104: Participant assessment.

In general, NPA agrees with CMS that initial comprehensive assessments and reassessments should be conducted "in-person." NPA requests, however, that CMS allow for the possibility that an interdisciplinary team member may use video technology to conduct a "face-to-face" assessment in which the participant and the IDT member interact "face-to-face" and in real time but from different physical locations. Although we do not expect this practice to be widespread, we can envision the benefits of such an approach, particularly in rural areas where distances and travel times may be great, and would not want the requirement for an "in-person" assessment to preclude this approach for either initial assessments, or subsequent semiannual and unscheduled reassessments.

§460.132: Quality assessment and performance improvement plan.

NPA concurs with CMS' proposal to specify that the PACE organization's quality improvement plan must be "collaborative and interdisciplinary in nature." We believe this term accurately describes the quality improvement plans currently in place at PACE organizations.

§460.150: Eligibility to enroll in a PACE program.

NPA concurs with clarifying that the criteria used by PACE organizations to determine if an individual's health or safety would be jeopardized by living in a community setting are developed by the State administering agency.

§460.156: Other enrollment procedures.

NPA concurs with CMS' proposal to eliminate the requirement for PACE organizations to give a new PACE participant sticker(s) for his or her Medicare and Medicaid card, as applicable, and to require that the PACE membership card indicate that he or she is a PACE participant and include the phone number of the PACE organization.

§460.162: Voluntary disenrollment and §460.112: Specific rights to which a participant is entitled.

NPA supports CMS' objective to effectuate voluntary disenrollments as quickly as possible after a PACE participant has notified a PACE organization that he or she would like to voluntarily disenroll. We are concerned, however, that states' enrollment/disenrollment systems may not allow for disenrollment from a PACE program to be effective the first day of the following month if notice is given beyond a certain day of the month. While it is always possible to disenroll a Medicare-only beneficiary effective the first day of the month following notification, for Medicaid-only and dual-eligible PACE participants, disenrollment from PACE involves states' Medicaid enrollment/disenrollment systems which may require notification to be provided in advance of a "cutoff date" in order for a disenrollment to be effective the first of the following month. In these situations, it may not be possible to disenroll a Medicaid-only PACE participant or coordinate the disenrollment date between Medicare and Medicaid for dual-eligible PACE participants as required by §460.166(a)(2) until the first day of the 2nd following month. Therefore, in recognition of differences in states' enrollment/disenrollment systems, we recommend retaining the current regulatory requirements in §460.166 to: 1) use the most expedient process allowed under Medicare and Medicaid procedures, and 2) coordinate the disenrollment date between Medicare and Medicaid (for a participant who is eligible for both Medicare and Medicaid).

§460.164: Involuntary disenrollment.

In regard to CMS' proposal that involuntary disenrollments should be 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, NPA agrees with CMS that PACE participants should receive adequate advance notice of an involuntary disenrollment and concurs with CMS' proposed change with one exception. We request that CMS allow for involuntary disenrollments to take effect as quickly as possible after the PACE organization meets its requirements and sends notice of the disenrollment to the participant in

situations in which a PACE participant is out of the PACE organization's service area for more than 30 days without prior notice or approval. While out of the PACE organization's service area, the participant does not have access to the PACE organization and its providers. Further, while enrolled in PACE, he/she is unable to access alternative Medicare and Medicaid coverage. Delaying enrollment for as long as two months after the notice of disenrollment is sent is not in the best interest of either the participant or the program which retains risk for catastrophic costs resulting from the participant's need for emergency care.

NPA concurs with CMS' proposal to add two reasons for involuntary disenrollment: (1) after a 30-day grace period, failure to pay or failure to make satisfactory arrangements to pay any applicable Medicaid spenddown liability or any amount due under post-eligibility of income processes, and (2) in situations where the participant's caregiver (including any family member involved in the participant's care) engages in disruptive or threatening behavior such that this behavior jeopardizes the participant's health or safety, or the safety of the caregiver or others.

§460.182: Medicaid payment.

In response to CMS' proposal to add a new requirement that the Medicaid payment, "is sufficient and consistent with efficiency, economy and quality of care," NPA supports CMS' proposed change to require that Medicaid rates be sufficient to provide the services required under the PACE program for the population enrolled. This addresses the need for States to set rates that take into account that PACE organizations are responsible and at full financial risk for all Medicaid covered services, including nursing home care, and that the population enrolled in PACE is a high-need, high-cost subset of dual-eligible and Medicaid-only beneficiaries. To clarify this further, we suggest that CMS include an additional requirement of Medicaid capitation payments under §460.182(b), i.e., that they take into account that PACE organizations are responsible and at full financial risk for all Medicaid covered services, including risk for nursing home care without a restriction or rate adjustment for length of stay.

Further, state rate setting should recognize subpopulations with distinctly different cost experiences, e.g., dual eligible vs. Medicaid-only beneficiaries, beneficiaries with Medicare Part A or Part B only, age cohorts, beneficiaries with significant behavioral health diagnoses, and establish distinct rates accordingly. In the absence of these distinct rates, PACE organizations are unnecessarily at risk due to a distribution of PACE participants that is not consistent with the distribution of the subpopulations used to calculate a single, or overly broad, aggregated rate.

For future rule-making, CMS is requesting comments about other rate methodologies CMS may consider requiring for Medicaid capitation payment amounts for PACE and whether 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. Although we are not ready to recommend alternative rate methodologies at this time, we appreciate this opportunity to share with CMS some of points raised by members of a workgroup NPA recently convened on Medicaid rate-setting for PACE. The group did discuss the implications of requiring actuarially sound rates for PACE.

If actuarially sound rates were required, it is critical that the rates fully account for the characteristics of the population enrolled in PACE, the comprehensiveness of the services provided, and PACE organizations' assumption of full financial risk for all care including long-term nursing home placement. Although there are similarities between PACE and many of the state financial alignment demonstrations, there are differences in regard to these key elements which have significant implications for rate-setting. As a result, it may be difficult to utilize rates established for the financial alignment demonstrations for PACE organizations. Other issues that were discussed by the workgroup include: 1) the cost to the state of developing actuarially sound rates; and 2) the possibility that an actuary may not be able to certify rates for PACE due to the small size of the program. We have also heard that movement to actuarially sound rates may increase the transparency of a state's rate-setting approach which is something we support.

§460.190: Monitoring during trial period.

In response to CMS' proposal to use more remote technology in conducting annual trial period reviews of PACE organizations, NPA generally concurs with CMS' proposed changes to the trial period review process and is hopeful that increased use of remote technologies will result in more efficient use of resources for both CMS and PACE organizations. We would like to offer a specific comment in regard to expectations of PACE organizations "to provide CMS access to information on its computer systems in real time, in a secure manner." Admittedly, we are not entirely familiar with the details of the technology that CMS references in the proposed rule, but it may be appropriate to refer to correspondence between CMS and NPA in June and July, 2015. At that time, we expressed concern to CMS that current EHR systems of PACE organizations were not designed to manage remote access. In response, CMS indicated that, "the PO must work directly with CMS in order to determine an alternative means, including paper copies, to provide CMS access to the PO's records as required by the PACE regulations and consistent with the timelines required by CMS." It is essential that alternative means of providing CMS access be retained for PACE organizations in situations where providing remote access is not possible or costly. While this may be possible for most or all Medicare Advantage organizations and Part D sponsors, there are significant differences between PACE organizations, and MA organizations and Part D sponsors in regard to their systems.

§460.192: Ongoing monitoring after trial period.

NPA agrees with CMS that onsite reviews are not necessary for all PACE organizations every two years. We would, however, appreciate additional information on the criteria that CMS will use to identify PACE organizations to be audited/reviewed and, in particular, the criteria that will be used to conduct repeated audits/reviews of a particular PACE organization.

§460.194: Corrective action.

NPA concurs with CMS' proposal to clarify that PACE organizations must take action to correct deficiencies identified by CMS or the SAAs as a result of the following: (1) ongoing monitoring of the PACE organization, (2) reviews and audits of the PACE organization, (3) complaints from PACE

participants or caregivers, and (4) any other instance CMS or the SAA identifies programmatic deficiencies requiring correction.

§460.196: Disclosure of review results.

CMS proposes to amend §460.196(d) to ensure that PACE organizations make results of reviews of PACE organizations readily accessible to not only participants, but also their families, caregivers and authorized representatives. NPA agrees that review results should be accessible to both participants and others who may be involved in their care. We are concerned, however, that review results generally focus on program deficiencies and typically do not include positive remarks on those aspects of program performance that are compliant and, in some cases, exceedingly so. Consequently, review results can give an inappropriately negative impression of the program. We ask that CMS take steps to assure that the review results provide a more comprehensive impression of program performance.

§460.200 Maintenance of records and reporting of data.

NPA concurs with CMS' proposal to modify record retention requirements from 6 to 10 years in §460.200(f)(ii) and (iii).

Thank you again for the opportunity to provide comments on the proposed rule for PACE. Please direct any questions you have to Chris van Reenen, Vice President for Regulatory Affairs at chrisvr@npaonline.org or (703) 535-1568.

Sincerely,



Shawn M. Bloom
President and CEO

Exhibit 1

NPA's Proposed Revisions to Sections 460.102, 460.104 and 460.106

§460.102 Interdisciplinary team.

(a) *Basic requirement.* A PACE organization must meet the following requirements:

(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 [reassess each participant through the use of applicable assessment teams pursuant to the requirements of section 460.104 and](#) meet the individual needs of [each participant through plans of care established by applicable care planning teams under section 460.106 for](#) each participant.

(2) Assign each participant to an interdisciplinary team ~~functioning at the PACE center that the participant attends.~~

(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. [With respect to each individual participant, the members of the IDT responsible for the care of that participant shall be determined based on the care plan developed by the applicable care planning team for the participant under section 460.106.](#)

(1) Primary care- provider.

(2) Registered nurse.

(3) Master's-level social worker.

(4) Physical therapist.

(5) Occupational therapist.

(6) Recreational therapist or activity coordinator.

(7) Dietitian.

(8) PACE center manager.

(9) Home care coordinator.

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

(11) Driver or his or her representative.

(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, [including such a physician assistant who is community-based.](#)

(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, [including such a nurse practitioner who is community-based.](#)

(2) Each primary care- provider is responsible for the following:

(i) Managing a participant's medical situations.

(ii) Overseeing a participant's use of medical specialists and inpatient care.

(d) *Responsibilities of interdisciplinary team.* ~~(1) The~~(1) Subject to the requirements of sections 460.104 and 460.106, the interdisciplinary team is responsible for the initial assessment, periodic reassessments, plan of care, and coordination of 24 hour care delivery.

(2) Each team member is responsible for the following:

(i) Regularly informing the interdisciplinary team of the medical, functional, and psychosocial condition of each participant.

(ii) Remaining alert to pertinent input from other team members, participants, and caregivers.

(iii) Documenting changes of a participant's condition in the participant's medical record consistent with documentation policies established by the medical director.

~~(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.

(f) Exchange of information between team members. The PACE organization must establish, implement, and maintain documented internal procedures governing the exchange of information between team members, contractors, and participants and their caregivers consistent with the requirements for confidentiality in §460.200(e).

§460.104 Participant assessment.

(a) Core assessment team— (1) Composition of core assessment team. A PACE organization shall establish a core assessment team consisting of the following members of the interdisciplinary team:

- (i) Primary care provider.
- (ii) Registered nurse.
- (iii) Master's-level social worker.
- ~~(a)~~ _____

(2) Applicable assessment team.—In this section, the term “applicable assessment team” means, with respect to an assessment or reassessment of a participant, the following:

(i) With respect to an initial comprehensive assessment under paragraph (b)(1) of this section, the initial comprehensive assessment team described in paragraph (b)(2) of this section.

(ii) With respect to a semiannual reassessment under paragraph (d)(1) of this section, the semiannual reassessment team described in such paragraph (d)(1).

(iii) With respect to an annual reassessment under paragraph (d)(2) of this section, the annual reassessment team described in such paragraph (d)(2).

(iv) With respect to an unscheduled reassessment due to a participant’s change in status under paragraph (e)(1) of this section, the unscheduled reassessment team described in such paragraph (e)(1).

(v) With respect to an unscheduled reassessment due to a service request under paragraph (e)(2) of this section, the unscheduled reassessment team identified in such paragraph (e)(2).

(b) Initial comprehensive assessment—(1) Basic requirement. ~~The interdisciplinary~~The initial comprehensive assessment 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)(c)~~ of this section.

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

- (i) Primary care provider~~The core assessment team.~~
- (ii) Registered nurse.
- ~~(iii) Master's-level social worker.~~
- ~~(iv)~~ Physical therapist.
- ~~(viii)~~ Occupational therapist.
- ~~(xiiiv)~~ Recreational therapist or activity coordinator.
- ~~(xiiiv)~~ Dietitian.
- ~~(xiiiv)~~ Home care coordinator.

(3) Additional professional disciplines.—At the recommendation of ~~the interdisciplinary~~core assessment team members, 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:

- (i) Physical and cognitive function and ability.
- (ii) Medication use.
- (iii) Participant and caregiver preferences for care.
- (iv) Socialization and availability of family support.
- (v) Current health status and treatment needs.
- (vi) Nutritional status.
- (vii) Home environment, including home access and egress.
- (viii) Participant behavior.
- (ix) Psychosocial status.
- (x) Medical and dental status.
- (xi) Participant language.

~~(b)~~ *Development of plan of care.* Within 30 days of the date of enrollment, the [interdisciplinary initial comprehensive assessment](#) team [under paragraph \(b\)\(2\) of this section](#) must consolidate discipline-specific assessments into a single plan of care for each participant through team discussions and consensus of the entire [interdisciplinary initial comprehensive assessment](#) 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, 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.

~~(d)~~ *Periodic reassessment—(1) Semiannual reassessment.* On at least a semiannual basis, or more often if a participant's condition dictates, the [semiannual reassessment team \(composed of the following members of the interdisciplinary team\)](#) must conduct an in-person [semiannual](#) reassessment:

~~(i) Primary care provider.~~

~~(ii) Registered nurse.~~

~~(iii) Master's level social worker.~~

~~(iv) 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)(i) The core assessment team.~~

~~(ii) At the recommendation of the core assessment team members, other members of the interdisciplinary team (for example, home care coordinator, physical therapist, occupational therapist, or dietitian) may be included in the semiannual reassessment.~~

~~(2) Annual reassessment.~~ On at least an annual basis, the [annual reassessment team \(composed of the following members of the interdisciplinary team\)](#) must conduct an in-person annual reassessment:

~~(i) The core assessment team.~~

~~(ii) Physical therapist or occupational therapist.~~

~~(iii) At the recommendation of the core assessment team members, other members of the interdisciplinary team may be included in the annual reassessment.~~

~~(e) Unscheduled reassessments.~~ In addition to [annual and](#) semiannual reassessments, unscheduled reassessments may be required based on the following:

~~(1) A change in participant status.~~ If the health or psychosocial status of a participant changes, the [unscheduled reassessment team \(composed of the following members of the interdisciplinary team listed in paragraph \(e\) of this section\)](#) must conduct an in-person reassessment:

~~(i) The core assessment team.~~

~~(ii) Physical therapist or occupational therapist.~~

(iii) At the recommendation of the core assessment team members, other members of the interdisciplinary team may be included in the unscheduled 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 unscheduled reassessment team (composed of the members of the interdisciplinary team listed in paragraph (c) of this section that are related to the service request, as identified by the core assessment team), must conduct an in-person reassessment.

(i) The PACE organization must have explicit procedures for timely resolution of requests by a participant or his or her designated representative to initiate, eliminate, or continue a particular service.

(ii) Except as provided in paragraph (d)(2)(iii) of this section, the interdisciplinary core assessment team must notify the participant or designated representative of its decision to approve or deny the request from the participant or designated representative as expeditiously as the participant's condition requires, but no later than 72 hours after the date the interdisciplinary core assessment team receives the request for reassessment.

(iii) The interdisciplinary core assessment team may extend the 72-hour timeframe for notifying the participant or designated representative of its decision to approve or deny the request by no more than 5 additional days for either of the following reasons:

(A) The participant or designated representative requests the extension.

(B) The core assessment team documents its need for additional information and how the delay is in the interest of the participant.

(iv) The PACE organization must explain any denial of a request to the participant or the participant's designated representative orally and in writing. The PACE organization must provide the specific reasons for the denial in understandable language. The PACE organization is responsible for the following:

(A) Informing the participant or designated representative of his or her right to appeal the decision as specified in §460.122.

(B) Describing both the standard and expedited appeals processes, including the right to, and conditions for, obtaining expedited consideration of an appeal of a denial of services as specified in §460.122.

(C) Describing the right to, and conditions for, continuation of appealed services through the period of an appeal as specified in §460.122(e).

(v) If the interdisciplinary core assessment team fails to provide the participant with timely notice of the resolution of the request or does not furnish the services required by the revised plan of care, this failure constitutes an adverse decision, and the participant's request must be automatically processed by the PACE organization as an appeal in accordance with §460.122.

~~(e)(f)~~ *Changes to plan of care.* ~~Team~~The members of the applicable assessment team (as defined in paragraph (a)(2) of this section) who conduct a reassessment must meet the following requirements:

(1) Reevaluate the participant's plan of care.

(2) Discuss any changes in the plan with the ~~interdisciplinary team;~~ applicable care planning team (as defined in section 460.106(a)(2)).

(3) Obtain approval of the revised plan from the ~~interdisciplinary~~applicable care planning team (as defined in section 460.106(a)(2)) and the participant (or designated representative).

(4) Furnish any services included in the revised plan of care as a result of a reassessment to the participant as expeditiously as the participant's health condition requires.

~~(f)~~ *Documentation.* ~~Interdisciplinary~~The members of the applicable assessment team ~~members~~(as defined in paragraph (a)(2) of this section) must document all assessment and reassessment information in the participant's medical record.

§460.106 Plan of care.

(a) *Basic requirement.* (1) General requirement for care plans.

(i) A PACE organization shall develop or revise plans of care for each participant through the use of the applicable care planning team (as defined in paragraph (a)(2) of this section).

(ii) Within 30 days of the date of enrollment of each participant, the interdisciplinary applicable care planning team members specified described in §460.104 paragraph (a)(2)(i) of this section must develop an initial comprehensive plan of care for each the participant based on the.

(2) Care planning teams. In this section, the term “applicable care planning team” means the following:

(i) With respect to an initial comprehensive assessment findings under section 460.104(b), the applicable care planning team shall consist of the initial comprehensive assessment team described in 460.104(b)(2).

(ii) With respect to a semiannual reassessment under section 460.104(d)(1), the applicable care planning team shall consist of the following:

(A) The semiannual reassessment team described in such section 460.104(d)(1), and

(B) Other members of the interdisciplinary team that the core assessment team (described in section 460.104(a)(1)) determines are actively and substantively involved in the participant’s care.

(iii) With respect to an annual reassessment under section 460.104(d)(2), the applicable care planning team shall consist of the following:

(A) The annual reassessment team described in such section 460.104(d)(2), and

(B) Other members of the interdisciplinary team that the core assessment team (described in section 460.104(a)(1)) determines are actively and substantively involved in the participant’s care.

(iv) With respect to an unscheduled reassessment due to a participant’s change in status under section 460.104(e)(1), the applicable care planning team shall consist of the following:

(A) The unscheduled reassessment team described in such section 460.104(e)(1), and

(B) Other members of the interdisciplinary team that the core assessment team (described in section 460.104(a)(1)) determines are actively and substantively involved in the participant’s care.

(v) With respect to an unscheduled reassessment due to a service request under section 460.104(e)(2) of this section, the applicable care planning team shall consist of the following:

(A) The core assessment team (described in section 460.104(a)(1)).

(B) The unscheduled reassessment team identified in such section 460.104(e)(2), and

(C) Other members of the interdisciplinary team that the core assessment team (described in section 460.104(a)(1)) determines are actively and substantively involved in the participant’s care.

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

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

(2) Identify measurable outcomes to be achieved.

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

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

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

(c) *Implementation of the plan of care.* (1) The team must implement, coordinate, and monitor the plan of care whether the services are furnished by PACE employees or contractors.

(2) The team must continuously monitor the participant's health and psychosocial status, as well as the effectiveness of the plan of care, through the provision of services, informal observation, input from participants or caregivers, and communications among members of the interdisciplinary team and other providers.

(d) *Evaluation of plan of care.* On at least a semi-annual basis, the [interdisciplinary applicable care planning team \(as defined in paragraph \(a\)\(2\) of this section\)](#) must reevaluate the plan of care, including defined outcomes, and make changes as necessary.

(e) *Participant and caregiver involvement in plan of care.* ~~The team~~ [The applicable care planning team \(as defined in paragraph \(a\)\(2\) of this section\)](#) must develop, review, and reevaluate the plan of care in collaboration with the participant or caregiver, or both, to ensure that there is agreement with the plan of care and that the participant's concerns are addressed.

(f) *Documentation.* The ~~team~~ [applicable care planning team \(as defined in paragraph \(a\)\(2\) of this section\)](#) must document the plan of care, and any changes made to it, in the participant's medical record.