By this letter, the National PACE Association (“NPA”), on behalf of itself and its members, is pleased to respond to the above cited Federal Register notice soliciting comment on the interim final rule, published by the Health Care Financing Administration (“HCFA”) on November 24, 1999, establishing requirements for pre-paid, capitated voluntary PACE provider programs. In this regard, NPA has provided general comments with respect to the regulation overall, as well as specific comments and recommendations on individual provisions of the regulation.

I. BACKGROUND

The opportunity to comment on the proposed PACE regulation marks a critical point in the history of the PACE model, which dates back more than twenty-five (25) years to the commencement of operations by On Lok Senior Health Services, located in San Francisco, as one of the country’s first adult day health care centers. On Lok originated in response to the needs of frail elderly individuals residing in its local community, and evolved into a comprehensive, fully integrated care delivery system motivated to ensure that such needs are satisfied. PACE demonstration programs have followed the same course. With strong support from Congress, HCFA and State agencies, PACE programs have received national and local recognition for both the
provision of high-quality services and the cost savings resulting from such provision. The successful expansion of PACE is dependent on the continued existence of a vital partnership among providers, HCFA, States and public representatives. NPA is committed to working towards this end and, in this context, responds to HCFA’s solicitation.

In 1994, NPA was founded to provide a focal point for a variety of activities critical to the continued success of the PACE demonstration model, specifically policy analysis and advocacy, education, quality assurance and research. Today NPA represents fifty-six (56) organizational members, including the twenty-five (25) entities which operate PACE programs and the seven (7) pre-PACE programs (which are operational as Medicaid prepaid health plans and likely will be among the first entities to apply for permanent provider status); the remaining NPA members are in varying stages of PACE program development ranging from exploratory to pre-operational. Since its inception, providers and others have viewed NPA as the primary organizational vehicle for the PACE model, as well as its providers and enrollees. NPA has sponsored regularly scheduled national meetings involving both its members and Federal and State policymakers; and, on behalf of PACE demonstration programs, NPA has participated in numerous meetings with Federal and State officials. Further, as the demonstration sites’ representative, NPA has testified frequently before Congress.

This comment submitted by NPA is the product of an inclusive process involving both the membership and leadership of NPA. Specifically, the initial draft of the comment was developed by the NPA Regulation Task Force, a group comprised of members representing the wide diversity of NPA’s membership in terms of size, sponsorship, geographic location, length of PACE program operations, etc. Subsequently, the initial draft underwent an intensive review and comment process by both the NPA Public Policy Committee and NPA’s Board of Directors, which resulted in both the development by the Regulation Task Force of a second draft and another round of detailed review and discussion by the Public Policy Committee and the Board. With respect to individual member participation, suggestions from each member organization were solicited actively throughout all stages of the comment development process, first following HCFA’s publication of the proposed regulation and, thereafter, in response to the various drafts of the comment. Lastly, the final comment received the unanimous support of NPA’s Board of Directors. Accordingly, NPA submits these comments regarding the proposed regulations establishing and implementing the PACE provider model.

II. GENERAL COMMENTS

NPA commends HCFA’s efforts in developing the PACE regulation implementing Sections 4801 through 4804 of the Balanced Budget Act of 1997 (the “BBA”). See Social Security Act (“SSA”) §1894, et seq.; 42 U.S.C. §1395eee, et seq.; see also SSA §1934 et seq.; 42 U.S.C. §1396u-4 et seq.; see also BBA (August 5, 1997), Pub. L. No. 105-33 §4803 & §4804. We especially applaud HCFA in its attempt to remain consistent with both Congress’ intent behind the passage of legislation
establishing PACE programs as permanent providers under the Federal Medicare program and as voluntary State options under the Medicaid program, as well as the clinical and administrative requirements developed internally for the current PACE demonstration programs and documented in the PACE Protocol. See PACE Protocol, On Lok, Inc. (December 1993, as amended April 14, 1995). We acknowledge that, in most areas, HCFA has achieved both of these goals. Therefore, although our comments are lengthy, they should not be interpreted as dissatisfaction with the regulation overall. As the recognized spokes-vehicle for PACE providers and enrollees, NPA is responding to HCFA’s solicitation for comment by providing a comprehensive list of suggestions.

As a preliminary matter, NPA has several general comments that apply to the regulation in its entirety. Although many of these comments also encompass areas of specific application, we believe they merit discussion at the outset. In particular, NPA is concerned that the regulation provides too little opportunity for PACE providers to demonstrate flexibility and innovation in the application of the PACE model. One of the hallmarks of the PACE demonstration program is its flexibility in permitting individual PACE sites to not only meet the unique needs of its particular participant population, but also to respond to local market conditions and State issues as they arise. Such flexibility has resulted in the development of considerable diversity among existing PACE programs. However, rather than incorporating the flexibility which is characteristic of such programs, the proposed regulation encompasses some degree of rigidity, i.e., mandating detailed personnel qualifications which may disadvantage PACE organizations in the hiring of qualified staff and, thus, in providing the best and highest quality care; requiring notification of all, rather than significant and material, issues that arise as part of the treatment process, which, although consistent with the Medicare + Choice requirements, may be too burdensome in the context of a plan of care that could change on a daily basis.

NPA acknowledges that the PACE Protocol, upon which portions of this regulation were based, contains detailed requirements describing the administrative and clinical operations of the PACE program. However, as the PACE program has developed, so has the Protocol, undergoing several revisions since its inception. Such modifications have been based primarily on operational needs which were not, and could not have been, anticipated prior to implementation of the demonstration program. For example, the original PACE Protocol required physical therapists to be employed directly by the PACE organization. However, in response to the inability by some PACE programs located in staff shortage areas to satisfy this requirement, the direct employment requirement was modified to permit contracting for physical therapists. Unlike the demonstration program, the regulatory process typically does not permit modification on a regular basis (and may, in fact, allow for such modification on an infrequent basis). Accordingly, as discussed in more detail throughout this comment, NPA requests that HCFA recognize and accommodate a more flexible and responsive approach to modification.
We recognize that one of Congress’ interests in passing legislation establishing PACE as a permanent provider was to normalize the availability of PACE programs to all eligible Medicare and Medicaid beneficiaries. However, we believe that Congress foresaw the need for continued flexibility and innovation with respect to the manner by which services are delivered to frail elderly beneficiaries under PACE programs. In this regard, Congress specifically authorized the Secretary, in consultation with the States, to “modify or waive provisions of the PACE Protocol as long as such modification or waiver is not inconsistent with and would not impair the essential elements, objectives, and requirements” of the statute and would not modify or waive the fundamental characteristics of the PACE model. See SSA §1894(f)(2)(B); 42 U.S.C. §1395eee(f)(2)(B); see also SSA §1934(f)(2)(B); 42 U.S.C. §1396u-4(f)(2)(B). These non-waivable/non-modifiable characteristics are as follows:

“(i) The focus on frail, elderly individuals who require the care provided in a nursing facility. (ii) The delivery of comprehensive, integrated acute and long-term care services. (iii) The interdisciplinary team approach to care management and service delivery. (iv) Capitated, integrated financing that allows the provider to pool payments received from public and private programs and individuals. (v) The assumption by the provider of full financial risk.” Id.1

NPA believes that, contrary to legislative intent, this flexibility was interpreted very narrowly in the regulation. Such narrow interpretation not only puts the PACE model at risk of stagnating, but also compromises the PACE provider’s ability to respond to the unique and constantly changing needs and preferences of the PACE participant, as well as State and local market conditions.

In the specific comments that follow, we suggest areas in which NPA believes that additional flexibility would be consistent with the legislative intent while not impeding the quality of services provided to PACE participants. In particular, we propose a broader use of the waiver/modification process authorized in the legislation, thereby permitting waiver of regulatory provisions in addition to those explicitly indicated and allowing consideration of waiver requests at times in addition to the initial application process. Further, consistent with certain regulations governing the delivery of health care and related services to populations similar to those served by the PACE program, we propose limiting the requirements contained in some sections of the proposed regulation, i.e. personnel qualifications.

The PACE legislation also provides that the Secretary may apply certain requirements of, among other programs, the Medicare + Choice program in establishing the PACE regulation. See SSA, §1894(f)(3)(A); 42 U.S.C. §1395eee(f)(3)(A); see also SSA §1934(f)(3)(A); 42 U.S.C. §1396u-4(f)(3)(A) (emphasis added). The Secretary, in

1 The flexibility granted by such authorization is consistent with the PACE Protocol, which incorporates a provision permitting waiver by HCFA and the State Medicaid agency of specific programmatic requirements “provided that, in their judgment, the intent of the requirement is met by the proposed alternative, and safe and quality care will be provided.” See PACE Protocol, Part IV.B.19, p.22.
applying such requirements, is authorized to consider factors such as the difference in populations served and benefits provided, as well as to not include any requirements that would either conflict with the ability of the provider to carry out the PACE program in accordance with the statute or restrict the proportion of enrollees eligible for benefits. See SSA §1894(f)(3)(B); 42 U.S.C. §1395eee(f)(3)(B); see also SSA §1934(f)(3)(B); 42 U.S.C. §1396u-4(f)(3)(B). NPA believes that, in many instances, HCFA has suitably applied such discretion, striking an appropriate balance between the requirements of the Medicare + Choice program and the PACE Protocol. However, NPA also believes that, in some circumstances, the regulation applies Medicare + Choice requirements in an inappropriate manner, i.e., without considering the differences between the two programs with respect to the relative size of each program and the populations served. Such application is contrary to the flexibility accorded the Secretary in the legislation. In the specific comments that follow, we will address individually such concerns.

The comments contained in Parts III and IV below address NPA’s concerns with respect to specific provisions of the proposed regulation. To assist HCFA in reviewing such comments, we have separated our remarks into two (2) broad categories: (1) major concerns, which are of great importance in ensuring the overall success of the PACE model; and (2) additional comments. Please note, however, that within each category, the comments are presented in numerical order, rather than in order of importance. NPA believes that, because of the uniqueness of each PACE program, it would be difficult to “rank” the individual concerns within each broad category in a manner consistent with the needs and expectations of all our member organizations.

III. MAJOR CONCERNS REGARDING SPECIFIC PROVISIONS

§460.46: Civil money penalties.

Section 460.46 establishes monetary penalties for violation by the PACE provider of certain requirements and duties. See 64 Fed. Reg. 66234, 66282; 42 C.F.R. §460.46. NPA recognizes the importance of imposing sanctions for non-compliant behavior and/or actions which are significant in size, not only as a remedy for such behavior/action, but also to deter future non-compliance. We are concerned, however, that the regulation provides for civil monetary penalties of the same or greater magnitude as those required of both Medicaid managed care plans and Medicare + Choice plans, which plans most likely encompass a greater number of participants, as well as a greater amount of revenue. See 63 Fed. Reg. 52022, 52089 (September 29, 1998); 42 C.F.R. §438.704, et.seq.; see also 42 C.F.R. §422.750(a)(1) and §422.758. In this regard, the penalty amounts proposed in §460.46(a), which, based upon the specific violation, range from $25,000 to $100,000, represent a much greater proportion of the PACE program’s revenue than the revenue of either the Medicaid managed care plan or the Medicare + Choice plan, effectively resulting in an imbalance with respect to monetary sanctions.
Accordingly, NPA encourages HCFA to recognize the size and revenue differential between PACE programs and typical Medicaid managed care plans and/or Medicare + Choice plans and to establish maximum civil monetary penalties proportionate to the size of the organization. Specifically, NPA believes the applicable penalty amounts should approximate one-fourth the amounts required for Medicaid managed care plans and/or Medicare + Choice plans. Accordingly, NPA requests that HCFA reduce the penalties specified in the proposed regulation as follows: (i) §460.46(a)(1): up to $25,000 plus $3,750 for each violation of §460.40(c) or (d); (ii) §460.46(a)(2): up to $6,250 plus double the excess amount above the permitted premium; (iii) §460.46(a)(3): up to $25,000 for each misrepresentation or falsification of information; and (iv) §460.46(a)(4): up to $6,250 for any other violation specified in §460.40.

§460.64: Personnel Qualifications and §460.66: Training.

Section 460.64 establishes the professional requirements for PACE program staff. See 64 Fed. Reg. 66234, 66283-66284; 42 C.F.R. §460.64. While NPA agrees that certain professional requirements are necessary, we have several comments regarding the priority and substance of the proposed requirements. First, NPA is concerned that the manner in which the requirements are presented in the proposed regulation does not appropriately emphasize that State licensing laws, State certification and State registration requirements take precedence over the requirements specified in §460.64(c). In turn, unnecessary and unintended conflicts between the PACE regulation and State requirements may result. In particular, NPA is concerned that the requirements set forth in such sections will be adopted as minimum Federal requirements, regardless of whether State licensure, certification, or other registration exists. If such adoption takes place, the PACE provider’s burden of locating adequate numbers of staff will be magnified. Accordingly, NPA proposes replacing the existing introductory paragraph to §460.64(c) with the following:

“Qualifications when no State licensing laws, State certification, or registration requirements exist. Qualifications for the following staff will be in accordance with the applicable State licensing laws, State certification or State registration requirements. In the event that State licensing laws, State certification or State registration requirements applicable to a particular profession do not exist, the following requirements must be met: ”

With respect to specific staffing requirements, NPA appreciates HCFA’s interest in assuring that PACE programs are staffed appropriately and, further, acknowledges HCFA’s right to establish certain requirements to support such interest. However, NPA believes that it is the ultimate obligation of the PACE provider to ensure the provision of care in an appropriate manner, which obligation encompasses fundamental staffing decisions. In this regard, NPA believes that the establishment by HCFA of the detailed requirements set forth in the proposed regulation unnecessarily limits flexibility in the development and implementation of PACE programs.
Specifically, NPA does not agree with the minimum prior experience requirements identified in §460.64(b)(2), §460.64(c)(1)(ii), §460.64(c)(2)(ii), §460.64(c)(3)(ii), §460.64(c)(4)(iv), §460.64(c)(6)(ii) and §460.64(c)(7)(ii). See 64 Fed. Reg. 66234, 66283-66284; 42 C.F.R. §460.64(b) & §460.64(c). NPA notes that such requirements were not included in the PACE demonstration program and their absence was not observed to be a problem vis-à-vis the provision of quality services in an efficient and effective manner. While NPA acknowledges the importance of an individual’s prior experience as a demonstration of his or her competency to perform a particular job, we are confident that PACE providers will take into account the value of such experience in making their hiring decisions regardless of whether such experience is required by regulation.

However, NPA opposes the imposition of a mandatory requirement that all physicians, registered nurses, social workers, physical therapists, occupational therapists and dieticians possess a minimum of one (1) year experience working with a frail or elderly population. Further, NPA opposes a requirement that all drivers be experienced in transporting individuals with special mobility needs. In particular, NPA is concerned that such requirements will result in a PACE provider’s inability to hire staff in adequate numbers to serve appropriately all participants (i.e., if, due to circumstances such as the program’s geographic location, persons with such experience are unavailable). Further, in situations under which individuals who satisfy the experience criterion are available, NPA is concerned that such prior experience will become the key factor in making hiring decisions, regardless of prospective employees’ other attributes. For example, because of the unique characteristics of PACE programs, as well as the participants served, the bilingual and culturally competent capabilities of individuals providing care-related services may be very important factors in a PACE organization’s employment decisions. However, placing an emphasis on experience may override such qualifications, thereby resulting in inappropriate staffing.

Accordingly, NPA proposes that HCFA delete the aforementioned experience requirements, granting the PACE provider discretion to hire appropriate staff based upon the program’s individual characteristics, as well as those of its participants. Please note that, in making such suggestion, NPA does not advocate the deletion of necessary educational requirements; nor does it desire to defer the responsibility of the PACE provider to hire qualified staff. Rather, we simply request the removal of the experience criteria which, in reality, may be untenable to achieve. Absent such modification, many existing (and future) PACE programs will not be able to comply fully with the regulatory requirements regarding personnel qualifications, which, in turn, may result in several programs “shutting their doors” or never becoming operational. Of course, in cases where an individual lacks experience, staff development procedures (e.g., mentoring and training programs) would be established and implemented for educational purposes.
In addition to the aforementioned comments which apply generally across a number of disciplines, NPA proposes several modifications to the requirements applicable to specific staff members. First, we encourage flexibility with respect to the requirement that social workers represented on the interdisciplinary team possess a master’s degree in social work. See 64 Fed. Reg. 66234, 66283; 42 C.F.R. §460.64(c)(2)(i). As an alternative to such requirement, NPA proposes personnel requirements consistent with those contained in applicable nursing home regulations. Specifically, NPA requests that HCFA modify this provision to state that the social workers must (1) hold a bachelor’s degree in social work or a bachelor’s degree in a human services field including but not limited to sociology, special education, rehabilitation counseling, and psychology; and (2) have one year of supervised social work experience in a health care setting working directly with individuals. See 42 C.F.R. §438.15(g). To account for the additional complexities of operating a PACE program (i.e., the complex behavioral and psycho-social issues present in the PACE participant population), each PACE organization would also employ or contract with a minimum of one (1) master’s level social worker.

NPA also believes that the requirements for recreation therapists or activities coordinators are too narrow and will impede the organization’s efforts to hire capable individuals to fill this position. See 64 Fed. Reg. 66234, 66284; 42 C.F.R. §460.64(c)(5). Accordingly, NPA recommends expanding such qualifications to require that a recreation therapist or activities coordinator be an individual who: (i) is a qualified therapeutic recreation specialist or an activities professional who is either licensed or registered under State law, if applicable, or is eligible for certification as such by a recognized accrediting body; or (ii) has two years of experience in a social or recreational program within the last five years, one of which was full-time in a patient activities program in a health care setting; or (iii) is a qualified occupational therapist or occupational therapy assistant; or (iv) has completed a training course approved by the State. See 42 C.F.R. §483.15(f).

Regarding the dietitian position, NPA proposes that, as an alternative to hiring a staff dietitian, each PACE organization should have the ability to contract with a dietitian who possesses the requirements set forth in the proposed regulations. See 64 Fed. Reg. 66234, 66284; 42 C.F.R. §460.64(c)(6). Such modification would be consistent with the requirement that each nursing home facility “employ a qualified dietician either full-time, part-time, or on a consultant basis.” See 42 C.F.R. §483.35(a).

Please note that several of our suggestions regarding particular personnel qualifications are consistent with the applicable definitions contained in nursing home regulations. Although nursing home regulations are typically restrictive, in the context of personnel qualifications, such regulations grant the nursing home latitude to employ or contract with those staff deemed necessary, in the discretion of the nursing home, to provide the best possible care to its residents. NPA simply requests that HCFA afford PACE providers the same flexibility it has previously granted to nursing homes.
Lastly, with respect to the personnel requirements for occupational therapists, NPA believes that the proposed regulation published on November 24, 1999 contains a typographical error. Specifically, we believe that HCFA intended that the requirements for occupational therapists include one of the educational requirements set forth in §460.64(c)(4)(i) through (iii), as well as the experience requirement set forth in §460.64(c)(4)(iv), rather than all four (4) of the requirements described in this sub-section of the proposed regulation. \(\text{See} \ 64 \text{Fed. Reg. 66234, 66283; 42 C.F.R. §460.64(c)(4)}\).

HCFA has also requested comment regarding whether to include specific personnel requirements for personal care attendants. \(\text{See} \ 64 \text{Fed. Reg. 66234, 66243. In response to such request, NPA concurs with HCFA’s decision not to mandate specific requirements for personal care attendants, but rather to extend PACE organizations the opportunity to establish requirements consistent with individual program needs and local market conditions.}

Further, with respect to HCFA’s requirement that PACE organizations establish a training program for personal care attendants to ensure they exhibit competency in furnishing basic personal care services, NPA believes it is important to remain flexible regarding such requirement. \(\text{See} \ 64 \text{Fed. Reg. 66234, 66284; 42 C.F.R. §460.66(b)}\). For example, some PACE organizations may choose to hire certified nursing assistants or home health aides to perform the duties of a personal care attendant. Under such circumstances, because the individuals hired will have been previously trained and certified in providing basic personal care services, NPA believes an appropriate training program would not include basic instruction on the provision of basic personal care services. However, in circumstances under which the individual hired has not participated in prior training and certification as a job requirement, NPA concurs that the PACE organization should have an appropriate training program in place. Accordingly, NPA recommends that the regulation recognize flexibility with respect to each PACE provider’s design of an appropriate training program(s), thereby permitting the provider to distinguish between the aforementioned scenarios.

\(\text{§460.80: Fiscal soundness.}\)

In general NPA agrees with the fiscal requirements set forth in §460.80. \(\text{See} \ 64 \text{Fed. Reg. 66234, 66286; 42 C.F.R. §460.80. Further, NPA appreciates HCFA’s acknowledgement that, based on the size of PACE organizations and the characteristics of their enrollee population, PACE organizations merit unique consideration with regard to fiscal requirements.}

NPA is concerned, however, that the regulation lacks a minimum amount to cover expenses in the event of insolvency. We recognize that the existing requirements set forth in §460.80(c) parallel those contained in the PACE Protocol. \(\text{See PACE Protocol, Part I.F, p.3. However, such solvency requirements were based on the existence of a risk sharing agreement between the PACE program, and the Federal and State governments, covering the program’s initial three years of operations. During this risk-sharing period, PACE programs’ financial exposure was limited. The solvency requirements stipulated} \)
in the Protocol were only effective upon the conclusion of the risk-sharing period, at a time when PACE programs typically had a census of 100 or more participants. Therefore, assuming an average total capitation payment of $3000 per participant, one month’s total capitation revenue equaled approximately $300,000. One month’s average payment to all contractors would contribute an additional $100,000.

Under PACE provider status, PACE organizations assume full financial risk from initial operations. Accordingly, to address this critical distinction between PACE provider organizations and entities which operated (or are still operating) under PACE demonstration authority, NPA recommends that the requirements established under §460.80(c)(1)(i) and (ii) equal, at a minimum, $250,000

§460.98: Service delivery.

As context for our comments regarding service delivery, NPA emphasizes that the essence of the PACE service delivery model is the interdisciplinary team which provides services to PACE participants, rather than the PACE facility or center. NPA and its member organizations strongly believe that the interdisciplinary team is the focal point or “glue” that holds the program together, resulting in the complete integration of benefits and services provided by PACE organizations, either directly or through sub-contracts. While we believe that the PACE center is a critical component of each PACE organization’s service delivery system, it should not be considered the core of the model. Such designation more appropriately belongs to the interdisciplinary team whose members provide services in a variety of locations including the PACE center, the home, inpatient facilities, and other alternative sites.

Such alternative locations do not substitute for the PACE center, a person’s home or inpatient facilities, but, rather, they allow the PACE organization to provide care to participants in a manner that is most responsive to each participant’s particular circumstances and needs. For example, recreational activities and certain other group activities may be more appropriately provided on-site in a designated area of a housing complex in which significant numbers of PACE participants reside. Obviously, this location does not substitute for the PACE center and should not be surveyed as such. Further, a PACE organization may establish specialized day centers to address the needs of participants with particular diagnoses, most notably Alzheimer’s or other types of dementia. Again, such day center would not substitute for the PACE center and such participants would be assigned to and attend a PACE center to receive, for example, primary care services. However, such participants would also attend the specialized center to receive social and recreational services specifically tailored to their needs as opposed to those of less cognitively impaired individuals.

NPA is concerned that the proposed regulation does not explicitly recognize the PACE organization’s ability to provide services at locations other than the PACE center, the home, and inpatient facilities. Section 460.98(2) requires that “services must be furnished in at least the PACE center, the home, and inpatient facilities.” See 64 Fed. Reg. 66234, 66287; 42 C.F.R. §460.98(2) (emphasis added). While such language does
not preclude the provision of services at additional locations, e.g., adult day health care centers and congregate housing complexes, NPA requests explicit recognition of service provision at alternative sites. In this regard, HCFA will acknowledge specifically the conceptual importance of the interdisciplinary team versus the PACE center, as well as the importance of alternative delivery sites in the PACE model of care. Further, such recognition will assist in avoiding potential adverse situations in which all alternative delivery sites are subject to PACE center regulatory requirements and survey criteria, in addition to any certification or licensure requirements applicable to such facilities. Accordingly, NPA requests that HCFA modify §460.98(2) as follows:

“These services must be furnished in at least the PACE center, the home and inpatient facilities. In addition, services may be provided in alternative locations provided they meet applicable State licensure and certification requirements.”

Further, NPA requests that HCFA clarify that all references to the “center” and center-related requirements, e.g., the requirement contained in §460.98(d)(3), reflect the PACE center solely, rather than encompassing the alternative service sites. Accordingly, NPA requests that HCFA modify each reference to “the center” contained in this section by placing the word “PACE” before such reference. For example, the revised §460.98(d)(3) would state “If a PACE organization operates more than one PACE center, each PACE center must offer the full range of services and have sufficient staff to meet the needs of participants” (emphasis added).

With respect to §460.98(b)(3), NPA requests that HCFA broaden the list of demographic categories under which the PACE organization cannot discriminate against a PACE participant. See 64 Fed. Reg. 66234, 66287; 42 C.F.R. §460.98(3). Specifically, NPA requests that HCFA include sexual orientation within such list.

§460.102: Multidisciplinary team.

NPA commends HCFA for its efforts to craft an extensive description of the interdisciplinary team consistent with the requirements set forth in the PACE Protocol. See 64 Fed. Reg. 66234, 66288; 42 C.F.R. §460.102; see also PACE Protocol, Part IV.B.3, p.18. As described in our comment regarding §460.98 Service Delivery, the interdisciplinary team is at the heart of the PACE model, and requirements that permit and encourage team members to work effectively in the interest of providing the highest quality participant care are paramount. In this regard, NPA has several concerns regarding specific elements of this provision.

Consistent with our earlier comments regarding the role of “PACE centers” (see comment regarding §460.98), NPA urges HCFA to consider flexibility with respect to the physical location in which the interdisciplinary team furnishes services. Although each participant will be assigned to a team which will be based at a PACE center, the team may furnish certain services at alternative locations. Accordingly, NPA requests that HCFA replace the phrase contained in §460.102(a)(2) requiring participant assignment to
a team “functioning at the PACE center that the participant attends” with a requirement that assignment be to a team “operating from” such center.

Of enormous importance, NPA requests that HCFA grant greater flexibility with respect to the existing requirement that all interdisciplinary team members be direct employees of the PACE organization. See 64 Fed. Reg. cites 66234, 66288; 42 C.F.R. §460.102(f). In reviewing the proposed regulation, NPA member organizations, including operational PACE demonstration programs, commented most frequently on the importance of allowing PACE organizations flexibility to contract with, rather than directly employ, the interdisciplinary team members addressed by §460.102(f). Such flexibility is sought for four primary reasons:

- local market conditions may make it impossible to hire staff, i.e., a market “shortage” of a particular discipline represented on the interdisciplinary team may limit the PACE organization’s ability to employ directly certain staff, resulting in the organization’s need to contract for such staff on a temporary or extended basis;

- circumstances may make it more desirable for a particular individual to contract with the PACE organization as opposed to enter into an employee relationship, i.e., such individual may desire to retain a university affiliation;

- specifically in the case of the primary care physician, the consumer, upon entering the PACE program, may prefer to continue receiving primary care from his or her historical/traditional physician rather than the PACE physician which, as the regulation is currently written, is effectively a condition of enrollment; and

- it may be more appropriate and desirable for a PACE organization to contract with another entity to provide PACE center services and interdisciplinary care management, which entity, in turn, would employ the team members.

As discussed in Part II of this comment, in drafting the PACE legislation, Congress explicitly indicated its intent and desire to afford the Secretary, in close consultation with the State administering agency, flexibility to modify or waive provisions of the PACE Protocol “so long as such modification or waiver is not inconsistent with and would not impair the essential elements, objectives, and requirements” of the statute. See SSA §1894(f)(2)(B); 42 U.S.C. §1395eee(f)(2)(B); see also SSA §1934(f)(2)(B); 42 U.S.C. §1396u-4(f)(2)(B). While the legislation sets forth specifically two (2) situations under which the Secretary and the State administering agency may exercise such authority, i.e., when a PACE organization is located in a rural area or when such organization determines it appropriate to use non-staff physicians, Congress intended such circumstances as illustrative, not exclusive.
Further, in response to the fourth situation described above, the PACE Protocol does not require that all team members be employees of the PACE organization. In fact, the Protocol states that “the following members of the team must be employees of the PACE provider or PACE Center: …” See PACE Protocol, Part IV.B.13.a, p.21 (emphasis added). The distinction in the Protocol between the PACE provider/organization and the PACE center is a crucial one; it recognizes the importance of ensuring that the interdisciplinary team interacts with participants at the service delivery level. However, it does not require team members to be employed by the PACE provider/organization itself.

Accordingly, NPA requests that HCFA modify the current requirement to expressly permit the PACE organization to directly employ, or contract with, the members of the interdisciplinary team. See 64 Fed. Reg. 66234, 66288; 42 C.F.R. §460.102(f).\(^3\) At a minimum, NPA requests that HCFA modify the waiver provision contained in §460.102(g) to permit waiver of the direct employment requirement for all team members, as the need arises. See 64 Fed. Reg. 66234, 66288; 42 C.F.R. §460.102(g). If HCFA grants our request, NPA strongly encourages HCFA to require PACE organizations to provide policies and processes for coordinating and integrating the entire range of PACE benefits, the extent of which will be governed by the function of the contracted staff and the degree of organizational oversight inherent in the position. For example, in circumstances under which contractors would essentially operate as employees, e.g., contract therapists who work at the PACE center and, for all intent and purposes, behave like employees of the PACE organization, it would be unnecessary to require elaborate documentation. Alternatively, more extensive documentation would be required of a PACE organization proposing to utilize non-staff physicians.

With respect to the role of the primary care physician, NPA believes it is critical that the regulations permit flexibility in the manner by which primary health care is delivered. See 64 Fed. Reg. 66234, 66288; 42 C.F.R. §460.102(c)(2). Specifically, NPA urges HCFA to acknowledge explicitly the role performed by the nurse practitioner and/or the physician assistant as a part of the PACE model for primary health care delivery. It has been previously demonstrated, both within the PACE model specifically and the health care system at large, that such individuals are very effective working in collaboration with the primary care physician.\(^4\) While NPA does not advocate that the nurse practitioner/physician assistant substitute for the primary care physician at all times, and certainly does not believe that such individuals should replace the PACE physician on the interdisciplinary team, nurse practitioners and physician assistants

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\(^3\) Regulations governing the operation of nursing homes and home health agencies provide precedent for flexibility in direct employment criteria. In both instances, the regulations expressly permit the organization to contract for key care-related staff members. See 42 C.F.R. §483.75(g); see also 42 C.F.R. §484.14(a). Therefore, NPA’s request for greater flexibility is consistent with HCFA’s prior policy permitting health care organizations to contract for key staff positions.

\(^4\) Please note that, under Medicare law, both nurse practitioners and physician assistants are recognized specifically as providers for reimbursement purposes.
should be utilized appropriately for the provision of primary care services. Accordingly, NPA requests that the role of the nurse practitioner/physician assistant be formally acknowledged in the regulation by adding the phrase “or a nurse practitioner/physician assistant working in collaboration with a PACE primary care physician, as reasonable, appropriate and allowable under State law and regulation” to all requirements promulgated in connection with the primary care physician’s role.

NPA is also concerned that, as drafted, the required responsibilities of the interdisciplinary team members apply “across the board” to all members, including personal care attendants and drivers, regardless of whether such members (both professional and non-professional) possess the same occupational and educational skills. See 64 Fed. Reg. 66234, 66288; 42 C.F.R. §460.102(d). Accordingly, NPA urges HCFA to grant flexibility with respect to the required responsibilities based upon whether a team member is a professional or a non-professional member. In particular, we request that HCFA: (i) ensure that appropriate procedures are established by which input from all members can be obtained (see 42 C.F.R. §460.102(d)(2)); and (ii) delete the requirement that all team members document in the medical record changes in the participant’s condition (see 42 C.F.R. §460.102(d)(2)).

With respect to the team, as a whole, NPA believes that, to adequately reflect the interaction among team members in connection with the development and implementation of participants’ treatment plans, the monitoring of treatment on an ongoing basis and the delivery of health care services, all references to the “multidisciplinary team” should be changed to the “interdisciplinary team.” Please note that, by changing the term to “interdisciplinary team,” the regulation would be consistent with the statutory provision which describes those elements of the PACE model that cannot be waived or modified. See SSA §1894(f)(2)(B)(iii); 42 U.S.C. §1395eee(f)(2)(B)(iii); see also SSA §1934(f)(2)(B)(iii); 42 U.S.C. §1396u-4(f)(2)(B)(iii).

HCFA has requested specific comment regarding its deviation from the PACE Protocol, requiring the inclusion of a “registered nurse” (as opposed to a “nurse”) on the interdisciplinary team. See 64 Fed. Reg. 66234, 66248. NPA supports such change.

HCFA has also requested specific comment regarding whether it is desirable to require the involvement of a geriatrician with the interdisciplinary team and, if so, whether the geriatrician should be employed by the PACE organization and primarily serve PACE participants. See 64 Fed. Reg. 66234, 66249. While NPA appreciates HCFA’s motivation for considering such requirement, for several reasons, it advises against its adoption. First, the majority of existing PACE physicians are internists or family practitioners who are well versed in the health care needs of PACE participants. Further, because of the limited availability of geriatricians, both nationally and even more so in specific localities, the imposition of such requirement would be impracticable, inappropriate and overly burdensome.
With respect to requiring the direct employment of geriatricians, as discussed in our prior comment regarding personnel qualifications (see comment regarding §460.64), HCFA should use caution in mandating restrictive qualification requirements that would take precedence over other attributes which may be important to a particular PACE program and the populations it serves. For example, a PACE organization that enrolls numerous non-English speaking individuals should have flexibility to consider whether a physician is bilingual, rather than whether he or she is a geriatrician, as a key factor in its hiring decisions.

Lastly, NPA would like to comment on the waiver process in general. While the regulation provides a process by which certain requirements can be waived, such process is merely a literal and, consequently, narrow interpretation of the expansive process delineated in the statute. See 64 Fed. Reg. 66234, 66288; 42 C.F.R. §460.102(g). As discussed above, the regulation simply duplicates the two (2) situations described in the statute under which waivers may be sought. However, Congress provided such circumstances by way of example, never intending them to function as exclusive waiver circumstances. Effectively, the regulation unnecessarily limits the PACE provider’s access to waivers. Further, because all waiver requests are made in conjunction with the PACE provider application, NPA is concerned that the regulation does not contain a process by which PACE providers may request and obtain waivers during the contract term.

Accordingly, NPA requests that, in addition to specifically including direct employment as a requirement subject to waiver, HCFA broaden the waiver process in its entirety by including the opportunity for PACE organizations to obtain waivers of other regulatory requirements in circumstances under which the PACE organization reasonably deems such waiver is necessary to implement and run the PACE program successfully. Further, we request an explicit acknowledgement that, after assuming operations, PACE providers will be permitted to apply for such waivers as their individual circumstances change and the need arises.

In this regard, HCFA has requested specific comment regarding whether the waiver provision permitting PACE organizations to utilize physicians who are not direct employees of the organization is too broadly defined. See 64 Fed. Reg. 66234, 66249-66250. For the reasons discussed above, NPA believes that the waiver provision is too narrowly defined, not providing PACE organizations adequate opportunity to develop alternative relationships with primary care physicians that successfully address the beneficiaries’ desire to retain their primary care physicians after enrolling in PACE, as well as establish the necessary lines of communication to assure integration. However, NPA believes that adoption of the aforementioned suggestion would resolve such issue.


Although NPA, in general, concurs with the requirements of §460.104, we propose a few modifications to this provision. See 64 Fed. Reg. 66234, 66288-66289; 42 C.F.R. §460.104. First, consistent with the preceding comment regarding the recognition
of nurse practitioners and physician assistants, NPA requests that HCFA modify both §460.104(a)(2)(i) and §460.104(c)(1)(i) by adding the phrase “or a nurse practitioner/physician assistant working in collaboration with a PACE primary care physician, as reasonable, appropriate and allowable under State law and regulation.”

Section 460.104(c)(3) sets forth the requirements regarding participant reassessment in connection with the plan of care based upon either a change in participant status or at the request of the participant or his or her designated representative. See 64 Fed. Reg. 66234, 66289; 42 C.F.R. §460.104(c)(3). NPA acknowledges the need to provide assessments in addition to those scheduled on a semiannual or annual basis and recognizes that, to be effective, a certain amount of structure must be incorporated into the reassessment process. However, we believe that the regulations, as drafted, delineate a rigid and administratively burdensome process, which could potentially paralyze the interdisciplinary team, thereby impacting adversely the provision of services. Since HCFA could not have intended such result, we urge HCFA to adopt the following revisions with respect to the reassessment process, recognizing that the type of reassessment performed should be based upon the degree or level of change in participant health status, rather than a “one size fits all” standard.

First, NPA requests that HCFA clarify that, to trigger a formal reassessment under §460.104(c)(3), a change in health status must be significant. Specifically, NPA proposes the following definition of “significant change,” consistent with the definition contained in nursing home regulation: “a “significant change” means a major decline or improvement in the participant’s status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the participant’s health status, and requires interdisciplinary review or revision of the care plan or both.” See 42 C.F.R. §483.20(b)(2)(ii).

Second, NPA requests that HCFA recognize that certain determinations with respect to changes to a participant’s plan of care do not require a formal full team assessment involving all team members identified in §460.104(a)(2).5 While all changes to the participant’s treatment plan should be discussed and reviewed by the full interdisciplinary team, NPA believes that, under certain circumstances, it may not be appropriate for every discipline represented on the team to perform an in-person reassessment. Accordingly, NPA requests that, consistent with the PACE Protocol, HCFA modify this provision to require that “appropriate members of the interdisciplinary team” perform reassessments in response to significant changes in a participant’s health status. See PACE Protocol, Part IV.B.9, p.20. Further, NPA requests that HCFA grant the PACE provider the discretion to determine the team members suitable to perform such reassessment.

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5 Our recommendation is consistent with nursing home regulation, which affords the nursing home discretion to determine whether and to what extent a reassessment or a change in care plan, or both, is necessary. See 42 C.F.R. §483.20(b)(2)(ii).
Third, NPA requests that HCFA distinguish between a reassessment initiated by the PACE organization based on a change in a participant’s health status and a request from the participant or his or her designated representative to initiate, eliminate or continue a particular service, to which the PACE organization will respond. While the former necessarily involves a re-evaluation of the participant and his/her current plan of care, the degree of re-evaluation involved with the later should be based upon the type of request received by the PACE provider. To ensure such distinction, NPA suggests that HCFA revise §460.104(c)(3) to reflect solely the PACE organization’s reassessment based on a change in participant status. Specifically, NPA requests that HCFA modify the title and first paragraph of this provision as follows:

“Reassessment based on significant change in participant status. If a participant experiences a significant change in his/her health or psychosocial status, appropriate members of the interdisciplinary team will conduct an in-person reassessment and revise the participant’s plan of care accordingly. For purposes of this section, “significant change” shall mean … [see above]. Regardless of the team members involved in the reassessment process, any modification to the participant’s care plan will be discussed and approved by the full interdisciplinary team.”

Further, the sub-sections describing the required procedures with respect to the PACE organization’s resolution of requests for changes in services should be deleted from this section of the regulation. See 64 Fed. Reg. 66234, 66289; 42 C.F.R. §§460.104(c)(3)(i) through (c)(3)(v).

In conjunction with the aforementioned, NPA suggests that HCFA draft a new section specifically addressing requests for changes in services initiated by the participant or his or her designated representative. HCFA, in drafting such section, should consider that the scope of services provided by the PACE organization may result in participant requests ranging from an additional meal delivered to their homes to permanent nursing home placement. Accordingly, NPA requests that HCFA: (i) recognize that, based upon the type of change requested, a range of PACE provider responses is acceptable; and (ii) explicitly grant PACE organizations flexibility to accommodate such range of responses. Specifically, NPA recommends that HCFA adopt a requirement that each PACE organization develop and establish a written policy specifying the different processes by which it will respond to requests for changes in services, based upon the type of request. Such policy will include criteria by which the PACE provider can determine whether a full reassessment is needed and will require PACE organizations to formally respond to such requests within a timeframe consistent with the participant’s health status. Further, the newly drafted requirement will include the resolution procedures deleted from the revised §460.104(c)(3), specifically subsections (i) through (v).

HCFA has requested comment regarding whether the regulations should include a specific timeframe for providing the changes in service identified through the reassessment process and contained in the revised plan of care resulting from such identification. See 64 Fed. Reg. 66234, 66251. Due to the difficulty in standardizing the amount of time needed to institute such changes, NPA concurs with the existing
requirement that such services “be furnished to the participant as expeditiously as the participant’s health condition requires.” See 64 Fed. Reg. 66234, 66289; 42 C.F.R. §460.104(d)(4).

HCFA has also requested comment regarding whether to impose a timeframe with respect to the frequency with which the PACE organization should review care plans with participants. See 64 Fed. Reg. 66234, 66252. Pursuant to the proposed regulations, each participant’s needs are reassessed, at a minimum, semiannually and care plans are updated as a result of such reassessments. See 64 Fed. Reg. 66234, 66289; 42 C.F.R. §460.106(d). NPA believes that it is unnecessary to impose additional timeframes with respect to the frequency of review and, further, appreciates the flexibility currently afforded the PACE organization with respect to such frequency.

§460.164: Involuntary disenrollment.

In general, NPA concurs with the involuntary disenrollment requirements set forth in this section. See 64 Fed. Reg. 66234, 66294; 42 C.F.R. §460.164. However, for the reason discussed below, NPA requests that HCFA expand the reasons for involuntary disenrollment contained in §460.164(a)(1) to include failure to pay any allowable fees and share of costs after a thirty (30) day grace period, including amounts required as part of “spenddown liability” and/or post eligibility treatment of income amounts.

NPA believes that by not permitting PACE organizations to involuntarily disenroll a participant who fails to pay any allowable fees and share of costs, such organizations are likely to be exposed to significant financial losses over extended periods of time. NPA recognizes that a Medicaid beneficiary who does not pay his or her share of cost may ultimately lose eligibility for Medicaid, thereby becoming liable for the PACE premium. Thereafter, if such participant fails to pay his or her premium, the PACE organization may invoke involuntarily disenrollment procedures for failure to pay the premium due the PACE organization. However, this can be a lengthy process during which the PACE program would be forced to absorb significant losses in revenue. At a minimum, the PACE organization would lose the amount of the cost share for the months the participant remained eligible for Medicaid plus the aggregate of the thirty (30) day grace period and the time required by the State to review the proposed involuntary disenrollment, which could total as much as two (2) months’ private pay capitation. Because individual cost shares and private pay premiums may exceed $1,000 and $2,500 per month, respectively, this loss of revenue could result in financial hardship to the PACE organization. Accordingly, we request that HCFA modify this section as proposed in the paragraph above.

In conjunction with the aforementioned comment, NPA requests that HCFA eliminate the requirement for State review of a participant’s involuntary disenrollment from PACE due to his or her failure to pay premium. As drafted, the regulation requires a thirty (30) day grace period before an involuntary disenrollment due to failure to pay premium becomes effective. See 64 Fed. Reg. 66234, 66294; 42 C.F.R. §460.164(a)(1). NPA believes that adding a review period to the current grace period would result in
financial hardship for the PACE organization. Further, because participants responsible for premium charge would be considered “private pay” beneficiaries, NPA believes that such individuals should be treated similar to the private insurance model, which does not incorporate a State review process with respect to enrollee disenrollment by the organization. Accordingly, NPA requests that HCFA qualify §460.164(e) by adding the following phrase to the beginning of the current sub-section: “Except under circumstances in which involuntary disenrollment is initiated by the PACE organization under §460.164(a)(1), …”

Further, HCFA has requested comment regarding whether it should establish a timeframe for the State administering agency’s review of proposed involuntary disenrollment proceedings. See 64 Fed. Reg. 66234, 66264. NPA proposes that, except when involuntary disenrollment is related to non-payment of premium (as described above), such review should be concluded within thirty (30) business days of submission of relevant documentation to the State administering agency. Further, NPA proposes an expedited review process of 72 hours, consistent with the timeframe for expedited review of appeals, for those cases in which the PACE organization reasonably determines that the participant’s health and safety may be serious jeopardized. With respect to involuntary disenrollment due to a participant’s nonpayment of share of cost, rather than nonpayment of premium, NPA suggests a timeframe of ten (10) business days. Lastly, NPA suggests that, in all cases where the State administering agency does not respond within the appropriate timeframe (so long as the PACE organization properly submits all relevant documentation), the involuntary disenrollment will be deemed approved.

§460.180: Medicare payment to PACE organization.

The proposed regulation sets Medicare payments to PACE providers “based on the rate [HCFA] pays to a Medicare + Choice organization.” See 64 Fed. Reg. 66234, 66295; 42 C.F.R. §460.180(a). However, NPA believes that Congress afforded the Secretary considerable latitude in establishing the Medicare payment methodology for PACE. Although the legislation identifies the Medicare + Choice payment methodology as a reference point in the development of the PACE payment methodology, the opportunity to pursue alternative options is permitted by inclusion of the provision “except as provided in this subsection or by regulations.” See SSA §1894(d)(1); 42 U.S.C. §1395eee(d)(1). We believe this option was included specifically to recognize the fact that the payment methodology for Medicare + Choice was still under development at the time BBA was enacted and knowledge of the impact of its application to PACE was unknown.

Accordingly, NPA strongly believes that the question of whether the Medicare + Choice payment methodology is an appropriate foundation for calculation of capitation payments to PACE providers is yet to be answered. In this regard, NPA praises HCFA’s acknowledgement of the problems inherent in applying the Principal In-Patient Diagnostic Cost Group (PIP-DCG) methodology to PACE and the decision to delay implementation of individual risk-adjustment to PACE until January 2002 at the earliest.
However, NPA must strongly emphasize that, based on the PACE program’s demonstrated impact on inpatient utilization, an individual risk-adjustment methodology that relies on inpatient diagnoses as a determinant of payment is completely inappropriate for PACE programs. Further, research demonstrates that reliance on diagnoses alone, even comprehensive diagnostic information collected in both inpatient and outpatient settings, is inadequate to account for Medicare costs for a frail elderly population with significant functional and cognitive impairments. Consequently, risk adjustment for PACE must account for PACE participants’ functional status and cognitive impairment as well as other factors that may systematically impact Medicare utilization and costs in the fee-for-service environment.

NPA also stresses the need to base a payment methodology (and related reporting system) for PACE programs on Medicare expenses incurred by comparable individuals outside PACE, not utilization of Medicare covered expenses by PACE participants themselves. Congress created permanent provider status for PACE programs in recognition of their success in providing services based on participants’ needs versus reimbursement potential. PACE programs have demonstrated their success in substituting a broad range of community-based services, not all of which are Medicare reimbursable, for high-cost inpatient care. Any efforts to base payments to PACE organizations on either inpatient and/or outpatient utilization of PACE participants, particularly if such utilization experience is limited to services reimbursable under Medicare, would be inconsistent with Congressional intent.

Because the regulation is not specific in regard to the manner in which Medicare + Choice rates will be established in the future or the manner in which HCFA will adjust Medicare + Choice rates for frailty and other factors determined by HCFA to be appropriate (see 64 Fed. Reg. 66234, 66295; 42 C.F.R. §460.180(b)(3) and §460.180(5)), it is difficult to offer specific comments beyond the aforementioned. Therefore, NPA requests that any process that HCFA employs to modify the current rate-setting methodology for PACE, i.e., county based per capita payments adjusted by a frailty factor of 2.39, include consistent and timely communication with PACE organizations. Further, NPA requests that HCFA seek input from NPA on the reasonableness and impact of proposed changes well in advance of a final determination regarding a particular rate-setting approach and its implementation.

With regard to payments to PACE organizations for Medicare participants who require ESRD services (see 64 Fed. Reg. 66234, 66295; 42 C.F.R. §460.180(4)), NPA is currently evaluating the impact of the change in the reimbursement methodology for PACE enrollees with ESRD as defined in the regulation. Our preliminary concerns with regard to the ESRD methodology presented in the regulation are twofold: (1) the use of age as a proxy for nursing home eligibility in defining the frailty adjuster to the statewide ESRD rate; and (2) the statewide nature of ESRD payment. We will be able to provide HCFA with more specific input after our evaluation is complete.
However, because of the critical nature of this issue and its implications for PACE programs, NPA requests that the timeframe for implementing any change in ESRD payment be extended to allow NPA and member sites adequate time to review and respond to the change in the ESRD payment methodology. Ideally, NPA requests that the revised payment methodology for ESRD be implemented with PACE demonstration sites’ transition to permanent provider status over the course of the next two (2) years. At a minimum, NPA requests that the timeframe for establishing the change in payment for ESRD enrollees be delayed from ninety (90) days to a minimum of six (6) months.

§460.186: PACE premiums.

As drafted, §460.186 establishes the premium for participants not eligible for Medicaid as equal to the Medicaid capitation amount (plus additional amounts depending on whether they are entitled to Medicare Part A or enrolled under Medicare Part B). See 64 Fed. Reg. 66234, 66296; 42 C.F.R. §460.186. NPA requests that HCFA clarify this section to provide that the premium for participants not eligible for Medicaid (“the Medicaid capitation amount”) be equal to the sum of the average capitation payment by the Medicaid agency and the average monthly participant share of cost, i.e., amount due under Medicaid spenddown and post-eligibility processes.6

NPA recognizes that §460.186, which defines the amount of monthly premium that a PACE organization can charge a participant, was drafted consistent with the PACE Protocol. See PACE Protocol, Part VI.D, p.26. However, NPA requests that the Secretary, within this section, exercise her authority to modify or waive provisions of the Protocol. See SSA §1894(f)(2)(B); 42 U.S.C. §1395eee(f)(2)(B); see also SSA §1934(f)(2)(B); 42 U.S.C. §1396u-4(f)(2)(B).

In general, NPA recommends that the rules governing private pay premium amounts be consistent with broader Medicare and Medicaid program requirements. NPA believes that Congress’ specific intent in establishing PACE as a permanent provider under Medicare and a State option under Medicaid was to expand the availability of PACE services. Toward that end, PACE organizations will strive to expand their enrollment beyond the dual eligible population that has historically constituted the significant majority of PACE participants. To achieve such expansion, PACE organizations need greater flexibility in establishing the private pay premium for the long-term care benefit than that which is afforded by the proposed regulation. Accordingly, NPA suggests that the PACE organization not establish private pay premiums for Medicare-covered services in excess of the Medicare capitation amount; nor should it establish private pay premiums for the long-term care benefit for non-Medicaid eligible participants which are below the Medicaid capitation amount, thereby

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6 In States where the participant share of cost is deducted from the Medicaid capitation rate to determine the State’s capitation payment, this sum is equal to the Medicaid rate. However, in States where participant share of cost is collected in addition to the Medicaid capitation rate, this sum is equal to the Medicaid capitation rate plus the average participant share of cost.
allowing PACE organizations to charge an amount greater than the Medicaid capitation amount.

§460.200: Maintenance of records and reporting of data and §460.208: Financial statement.

HCFA has specifically requested comment regarding the development of consistent financial reporting requirements between HCFA and State administering agencies. See 64 Fed. Reg. 66234, 66269-66270. At this juncture, NPA would like to comment regarding the broader coordination of reporting requirements.

NPA appreciates HCFA’s recognition of this issue and strongly encourages the greatest level of coordination possible in the establishment of reporting requirements for PACE organizations. See 64 Fed. Reg. 66234, 66296-66297; 42 C.F.R. §460.200 and 42 C.F.R. §460.208. Further, NPA recognizes the critical role of data in the oversight and monitoring of PACE operations by both HCFA and the State administering agency. However, NPA is concerned that potentially both HCFA and the State administering agency will apply a broad range of reporting requirements to PACE organizations which were developed for, and are more appropriate to, managed care entities and/or more limited provider types, e.g., home health agencies or nursing homes. While elements of these requirements are likely to have applicability to PACE, NPA discourages their wholesale application. In this regard, NPA is encouraged by HCFA’s support of the development of OBCQI requirements unique to PACE providers and encourages continued appreciation for the uniqueness of the PACE organization relative to other Medicare and Medicaid managed care programs and providers in connection with the development of future reporting requirements.

Further, NPA recommends that a PACE organization that is licensed and/or certified under State regulation as another provider entity in addition to its PACE provider status be eligible for a waiver of the Federal reporting requirements applied to that particular provider type, so long as comparable data is collected through the PACE program’s specific reporting requirements. For example, a subset of PACE demonstration programs are State licensed (and, in a smaller number of cases, Medicare certified) home health agencies. Presently, these entities are subject to OASIS reporting requirements, the purpose of which is to measure changes in outcomes over time with the explicit goal of improving quality of care. Because the data collected for OBCQI under the PACE program requirements serves the same purpose, NPA requests that once these programs are required to submit OBCQI data, they should no longer be subject to Federal OASIS requirements.

IV. ADDITIONAL COMMENTS REGARDING SPECIFIC PROVISIONS

§460.6: Definitions.

The definition of the PACE center contained in §460.6 of the proposed regulation does not include the full range of services that are available to PACE participants at the
PACE center, i.e., primary care services; social services; restorative therapies, including physical therapy and occupational therapy; personal care and supportive services; nutritional counseling; recreational therapy; and meals. See 64 Fed. Reg. 66234, 66280; 42 C.F.R. §460.6. However, the PACE center service delivery requirements contained in §460.98 require that each PACE center offer the full range of services. Accordingly, NPA recommends that HCFA modify the regulatory definition of “PACE center” to be consistent with such service delivery requirements. Specifically, NPA requests that HCFA adopt the definition contained in the PACE Protocol, which explicitly addresses the full range of services and benefits available at the PACE center. See PACE Protocol, Part IV.B.2.a. p.18.

§460.14: Priority consideration.

Section 460.14 establishes the process by which certain existing PACE demonstration programs, as well as programs that, while not yet operational, have applied for operational status, receive “priority consideration” with respect to the processing of applications for PACE provider status. See 64 Fed Reg. 66234, 66280; 42 C.F.R. §460.14. This provision implements the Congressional mandate to provide such organizations “priority consideration” during the three (3) year period beginning on the date of statutory enactment. See BBA, Pub. L. No. 105-33 §4803(c)(1). As you are aware, the PACE legislation was enacted on August 5, 1997, as part of the BBA. At that time, Congress mandated that HCFA publish the related implementing regulation by August 5, 1998. Thereafter, existing demonstration sites would be afforded an additional two (2) year transition period, until August 5, 2000, during which they would have priority status. Id. The regulation, consistent the statute, maintains such priority status until August 5, 2000.

Although consistent with the plain language of the statute, NPA believes that the process outlined in the regulation is inconsistent with the intent of the legislation. Legislative history indicates that, to provide PACE demonstration programs and their State administering agencies adequate time to transition, Congress intended to provide the demonstration programs with priority status for a two (2) year period following implementation of the regulation.7 However, because of the lengthy delay in such implementation, the period of priority status no longer coincides with the intended two (2) year transition period. Accordingly, NPA proposes that HCFA set aside for PACE demonstration programs twenty-six (26) of the eighty (80) provider slots currently authorized by the PACE legislation. This set aside should be effective for two (2) years

7 In particular, States must undertake a variety of activities, including modification of the State plan and review of the provider application, to allow a program to transition from demonstration to provider status. It may not be possible to complete these activities in time for priority sites to submit provider applications to HCFA by the current deadlines of January 10 or February 22, 2000.
commencing from the date the regulation was implemented, i.e., until November 24, 2001. 8

§460.16: Special consideration.

In addition to “priority consideration,” Congress mandated that certain organizations receive “special consideration” with respect to the PACE provider application process. Specifically, Congress required special consideration for entities that, through formal activities, have indicated a specific intent to become a PACE provider. See BBA, Pub. L. No. 105-33 §4803(c)(3). Section 460.16 implements this legislative provision. See 64 Fed Reg. 66234, 66280; 42 C.F.R. §460.16.

NPA concurs with the proposed regulation with respect to entities deserving of special consideration. However, we request that, because certain organizations have demonstrated their interest in pursuing PACE by signing feasibility contracts prior to May 27, 1997 and, subsequently, initiating operations, HCFA distinguish those organizations (currently designated as “Pre-PACE sites”) from other “special consideration” entities. Accordingly, NPA proposes specifically holding slots for the eight (8) pre-PACE sites. For the reasons discussed above, these slots should be set aside for two (2) years from the date the regulation was implemented. Together with the “priority consideration” sites, the total number of reserved slots would equal thirty-four (34), leaving forty-six (46) slots open to other organizations. Since NPA does not anticipate the number of entities applying for PACE provider status will exceed the current statutory limit of eighty (80), particularly in the two (2) year period beginning November 24, 1999, NPA’s proposed approach meets the legislative intent of defining “priority and special consideration” organizations, by permitting those organizations that have committed substantial resources and initiated operations to be “first in line” for provider status, while not foreclosing other entities from becoming PACE providers.

§460.60: PACE organizational structure.

Section 460.60 sets forth certain requirements with respect to the PACE organization. See 64 Fed. Reg. 66234, 66283; 42 C.F.R. §460.60. In particular, §460.60(c) requires the PACE organization to directly employ its medical director. Consistent with our prior comments with respect to the employment relationships of the interdisciplinary team members (see comment regarding §460.102), NPA believes that the PACE organization should be granted flexibility with respect to its employment of a medical director. Specifically, the regulation should expressly permit the PACE organization to contract for the services of its medical director, thereby enabling the

8 For purposes of the set-aside, NPA defines demonstration programs to include the twenty-five (25) programs currently operating under Medicare and Medicaid waiver authority along with the one (1) entity for which a waiver application has been submitted and is awaiting HCFA approval. The organizations that qualify for priority status, as well as the eight (8) pre-PACE sites discussed in our comment on §460.16, are included with this comment as Attachment 1.
organization to hire the most qualified individual for such position. Further, because the medical director position may not involve direct patient care and, consequently, may be part-time in nature, a contractual relationship should satisfy the needs of the PACE organization, its clinicians and its participants. Accordingly, NPA requests that HCFA modify §460.60(c) as follows:

“The organization must employ, or contract with, a medical director who is responsible for the delivery of participant care, for clinical outcomes, and for the implementation, as well as oversight, of the quality assessment and performance improvement program.”

Section 460.60(d)(3) requires a PACE organization to notify HCFA and the appropriate State administering agency at least sixty (60) days prior to the effective date of planned change in organizational structure. However, such requirement does not include a specific timeframe during which HCFA and the State administering agency must review such changes. Although a sixty (60) day timeframe may be implicit, NPA requests that HCFA modify this section to explicitly include such timeframe. Specifically, NPA requests that HCFA add the following to §460.60(d)(3):

“HCFA and the State administering agency must respond to the PACE organization providing notification of a planned change in organizational structure within 60 days of their receipt of such notice. If HCFA and the State administering agency do not respond within the 60 days response period, the PACE organization’s planned changes will be deemed approved.”

HCFA has also specifically requested comment on the following: (i) the importance of changes in organizational structure to participants; (ii) the types of structural changes of which participants should be notified; and (iii) the timing of such notification. See 64 Fed. Reg. 66234, 66241. From our experience, participants are not concerned with minor changes to the PACE program’s organizational structure. Accordingly, NPA recommends limiting participant notification of structural changes to those significant changes that directly impact the organization’s structure (e.g., changes in program ownership). In this regard, we would not consider changes in management structure or administrative personnel to be significant. Further, such notification should be provided in a timely manner, within a reasonable period of time after the change is executed and implemented.

§460.68: Program integrity.

Section 460.68 prohibits PACE programs from employing certain individuals under defined circumstances, including situations “where an individual’s contact with participants would pose a potential risk because the individual has been convicted of physical, sexual, drug, or alcohol abuse.” See 64 Fed. Reg. 66234, 66284; 42 C.F.R. §460.68. NPA applauds HCFA’s concern in this area and certainly would not consider employing individuals who may pose a threat to PACE participants. However, the proposed regulation is unclear regarding whether the potential risk to participants is
posed automatically because of an individual’s conviction or whether there is discretion on the part of the PACE program to make such determination, taking into account such conviction.

NPA advocates granting discretion to the PACE provider to determine whether an individual’s past convictions (which convictions vary greatly in type and severity) would pose a serious threat to PACE participants. Accordingly, NPA proposes that HCFA recognize explicitly the PACE program’s discretion by replacing the current §460.68(a)(3) with the following:

“In any capacity where, because of an individual’s prior conviction for physical, sexual, drug, or alcohol abuse, such individual’s contact with participants would, in the determination of the PACE provider, pose a potential risk to such participants.” (emphasis added).

§460.70: Contracted Services.

With respect to contracted services, HCFA has requested comment regarding whether the regulation should specify a prior notification requirement with respect to termination by the contractor of its subcontract with the PACE provider. See 64 Fed. Reg. 66234, 66244. NPA appreciates HCFA’s concern regarding the PACE participants’ receipt of medically appropriate care on a continuous and uninterrupted basis and, further, agrees with HCFA’s statement that “PACE organizations will contract with individuals and entities that understand and embrace the organization’s mission and commitment to participants.” Id. However, the proposed regulation addresses terms and conditions of subcontracts, including “methods of extension, renegotiation and termination,” and NPA assumes that notification requirements will be one such term. See 64 Fed. Reg. 66234, 66284; 42 C.F.R. §460.70(e)(4). Therefore, NPA believes that prior notification requirements with respect to a contractor’s termination of the subcontract are best left to negotiations between the PACE organization and the individual contractors.

§460.72: Physical Environment.

Based upon practical experience, NPA offers three (3) technical suggestions regarding the physical environment requirements set forth in this provision. First, NPA proposes that, to be consistent with the description of the facility contained in §460.72(a)(2), HCFA revise the designation of the facility from “Primary care clinic” to “PACE center.” See 64 Fed. Reg. 66234, 66285; 42 C.F.R. §460.72(a)(2).

Second, NPA requests that HCFA modify the requirement regarding equipment maintenance to state that PACE organizations, while required to maintain all equipment in good working order, are only required to establish, implement and maintain a written plan to ensure maintenance in accordance with manufacturer’s recommendations for equipment deemed to be life-sustaining and biomedical equipment. See 64 Fed. Reg. 66234, 66285; 42 C.F.R. §460.72(a)(3).
Lastly, in recognition of the fact that: (i) the definitions of “emergency equipment” and “emergency drugs” may vary in accordance with a particular PACE population’s needs, and (ii) PACE centers are not open on a 7-day, 24-hour basis, NPA requests that HCFA clarify §460.72(c)(4) to require the presence of equipment and drugs “necessary to provide adequate emergency care,” as well as the staff knowledgeable about the operation of such equipment and drugs, on the center’s premises only during the center’s hours of operation. See 64 Fed. Reg. 66234, 66285; 42 C.F.R. §460.72(c)(4).

§460.74: Infection control.

In general, NPA agrees with HCFA’s proposed requirements regarding infection control. See 64 Fed. Reg. 66234, 66285; 42 C.F.R. §460.74. However, recognizing that: (i) the PACE participant’s home is not under the control of the PACE organization; and (ii) the condition of a person’s residence involves the fundamental rights of autonomy and privacy of the home, NPA requests that HCFA modify §460.74(c)(1) by deleting the phrase “and in each participant’s place of residence.” Of course, as part of the overall treatment plan, each PACE organization will use best efforts to control infection in an individual participant’s home. However, the ability to control and prevent infection in such setting is subject to many influences, many of which cannot be controlled by the PACE organization. Consequently, NPA does not believe that such requirement should be mandated.

§460.78: Dietary services.

NPA offers two (2) technical suggestions regarding dietary services. See 64 Fed. Reg. 66234, 66285; 42 C.F.R. §460.78. First, to ensure that dietary needs are provided in accordance with the PACE participant’s treatment plan, NPA proposes that HCFA insert the following phrase at the beginning of §460.78(a)(1), §460.78(a)(2) and §460.78(a)(3): “[I]n accordance with each participant’s plan of care.” Further, to ensure patient freedom with respect to such meals, NPA suggests changing the term “provide each participant” to “offer each participant.” See 64 Fed. Reg. 66234, 66285; 42 C.F.R. §460.78(a).

§460.82: Marketing.

In general, NPA agrees with the marketing requirements set forth in this provision. See 64 Fed. Reg. 66234, 66286; 42 C.F.R. §460.82. However, to insure that all PACE participants are informed fully of the services they will receive from the PACE organization pursuant to the program, marketing materials should specify not only the covered benefits and services, but also the benefits and services excluded from the program (as defined in §460.96 of the proposed regulation).9 Accordingly, NPA proposes that §460.82(a)(1)(iii) be amended to state “[D]escriptions of benefits and services covered by the program, as well as those benefits and services excluded from the program.”

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9 The inclusion of excluded benefits and services would be consistent with recently proposed regulations governing Medicaid managed care. See 63 Fed. Reg. 52022, 52078; 42 C.F.R. §438.10(g)(1).
§460.100: Emergency care.

Section 460.100 sets forth certain coverage requirements for “urgently needed out-of-network services.” Specifically, such services are covered when they are prior authorized by the PACE organization or there is a failure by the organization to provide such authorization within one hour of an authorization request. See 64 Fed. Reg. 66234, 66287-66288; 42 C.F.R. §460.100(e)(2). However, the regulation does not propose a definition of “urgently needed services.” To assure that PACE organizations understand fully their responsibilities and liabilities under circumstances requiring prior authorization, NPA requests that HCFA explicitly define this term within the regulation as follows:

“Urgently needed care is covered services provided to a participant who is temporarily absent from the PACE organization’s service area (or, under certain circumstances, provided to a participant who is within the service area but neither the PACE organization nor one of its contracted providers is available or accessible) when such services are necessary and immediately required as a result of symptoms from an unforeseen illness, injury or condition which a prudent layperson, with an average knowledge of health and medicine, would reasonably believe requires such immediate attention.”

§460.112: Specific rights to which a participant is entitled.

Although, in general, NPA concurs with HCFA with respect to participants’ rights, we request three (3) minor amendments. Consistent with our comment regarding non-discrimination with respect to service delivery (see comment regarding §460.98), NPA requests that HCFA broaden the list of demographic categories under which the PACE organization cannot discriminate against a PACE participant to include sexual orientation within such list. See 64 Fed. Reg. 66234, 66290; 42 C.F.R. §460.112(a).

Also consistent with earlier comments regarding the information that should be specified in marketing materials (see comment regarding §460.82), NPA requests that HCFA modify §460.112(b)(1) to include the participant’s right to be informed fully of not only the services available from the PACE organization, but also those services excluded from coverage. See 64 Fed. Reg. 66234, 66290; 42 C.F.R. §460.112(b)(1). With respect to participant choice of providers, in recognition of certain limitations in connection with such choice (e.g., capacity restrictions), NPA requests that HCFA qualify §460.112(c)(1) as follows: “[T]o choose his or her primary care physician and specialists from within the PACE network, as accessible and feasible.” See 64 Fed. Reg. 66234, 66290; 42 C.F.R. §460.112(c)(1) (emphasis added).

HCFA has requested comment regarding whether the regulation should specify a notification timeframe with respect to the transfer of a participant to another part of the program. See 64 Fed. Reg. 66234, 66256. NPA appreciates the need to keep participants fully informed about treatment and believes that, as part of such information process, it is crucial that the PACE organization permit the participants’ active participation in care planning. However, the PACE provider must also maintain its ability to respond to
immediate changes in health status that may precipitate the need for a rapid transfer. Further, PACE organizations that are in the best position to determine which participants may need additional time in making a transfer and which would transfer without difficulty and upon comparatively short notice, must possess the flexibility to evaluate appropriate timeframes on a case-by-case basis. Accordingly, NPA advises against specifying a notification timeframe.

§460.120: Grievance process.

Although NPA, in general, concurs with the grievance process set forth in this section, we request one (1) qualification regarding the PACE provider’s responsibility to continue to provide services during the grievance process. See 64 Fed. Reg. 66234, 66291; 42 C.F.R. §460.120(d). Specifically, NPA requests that HCFA clarify §460.120(d) to state that, during the grievance process, the PACE organization must:

“[C]ontinue to furnish to the participant all services required by his/her current treatment plan. In the event that a change in health status necessitates a change in treatment plan, the PACE organization must furnish to the participant all services required by the revised treatment plan.”

§460.122: PACE organization’s appeals process.

Consistent with our prior comment regarding the grievance process (see comment regarding §460.120), we request a qualification regarding the PACE provider’s responsibility to continue to provide services during the appeals process. See 64 Fed. Reg. 66234, 66291; 42 C.F.R. §460.120(e)(2). Specifically, NPA requests that HCFA clarify §460.122(e)(2) to state that, during the appeals process, the PACE organization must:

“[C]ontinue to furnish to the participant all other services required by his/her current treatment plan. In the event that a change in health status necessitates a change in treatment plan, the PACE organization must furnish to the participant all services required by the revised treatment plan.”

Further, NPA requests that HCFA modify §460.122(h) to state that an adverse determination will be communicated to HCFA, the State and the participant “at the same time the decision is made and implemented.” See 64 Fed. Reg. 66234, 66292; 42 C.F.R. §460.122(h). While NPA recognizes and strongly supports the participant’s right to an external appeals process, we request that HCFA clarify the PACE organization’s right to implement its determination in connection with its internal appeals process, pending the outcome of the external appeals process. NPA believes the proposed modification achieves such clarification.

Lastly, HCFA has requested comment regarding the appropriateness of a thirty (30) day timeframe without extension within which the PACE provider must respond to participant appeals. See 64 Fed. Reg. 66234, 66257. For the reasons stated in the preamble, NPA concurs with the existing requirement as drafted.
§460.150: Eligibility to enroll in a PACE program.

Although NPA concurs with most of the eligibility requirements set forth in this provision, we disagree with HCFA’s interpretation of the statutory language establishing the PACE eligibility requirement related to age. See 64 Fed. Reg. 66234, 66293; 42 C.F.R. §460.150(b)(1). Under the PACE demonstration, each State establishes its particular minimum age for PACE eligibility at either 55 years of age or at an age higher than 55 years (but in no instance is the minimum age established below 55 years of age). For those States choosing to institute a minimum age requirement higher than 55 years (typically 65 years of age), their primary reasons are to avoid: (i) complexities in the Medicaid capitation rate-setting process which may occur when a population younger than 65 years of age is eligible for PACE enrollment; and (ii) State programmatic issues related to alternative programs for younger disabled persons.

NPA interprets the legislation to continue providing States the flexibility to determine their own minimum age requirement, so long as the requirement is not below 55 years of age. However, NPA believes that, contrary to the legislative intent, the regulation sets forth a categorical requirement of 55 years or older, thereby prohibiting States from making such determinations. Accordingly, we request that HCFA re-draft this section to account for such individual State determinations.

With respect to HCFA’s request for comment regarding the best method by which to implement the statutory requirement that individuals who enroll in a PACE program pursuant to provider status be comparable to those individuals who previously enrolled under the demonstration program, NPA concurs with HCFA’s interpretation of the statute. See 64 Fed. Reg. 66234, 66261-66262.

§460.152: Enrollment process

As a preliminary matter, commencing January 2002, Medicare + Choice enrollees will not be permitted to disenroll from their Medicare + Choice plan continuously and at any time throughout the year. However, the decision to enroll in PACE is often made in response to a sudden decline in health status and as an alternative to nursing home placement. The need for such rapid response may preclude delaying the decision until disenrollment from a Medicare + Choice plan is permitted once the lock-in provisions take effect. NPA advocates that HCFA explicitly permit qualified Medicare + Choice enrollees to disenroll at any point during the year for the purpose of enrolling in PACE. By providing such flexibility, the legislative provisions instituting a continuous PACE enrollment process would be realized.

With respect to the specific provisions of this section, NPA requests that HCFA qualify the information that must be included in the list of PACE organization employees furnishing care to participants, which list is provided to PACE participants during the intake process. See 64 Fed. Reg. 66234, 66293; 42 C.F.R. §460.152(a)(1)(iii). Insofar as such list could include hundreds of individuals, including personal care attendants and drivers, NPA is concerned with the breadth of such list and the potential difficulties in maintaining the accuracy and current status of such list. Accordingly, NPA requests that
HCFA modify §460.152(a)(1)(iii) as follows: “A list of employees of the PACE organization who furnish care as a member of an interdisciplinary team (with the exception of drivers and personal care attendants) ….”

§460.154: Enrollment agreement.

Although NPA, in general, concurs with the enrollment agreement requirements set forth in this section, we request two (2) qualifications to such requirements. First, consistent with our prior comments regarding covered services (see comments regarding §460.82 and §460.112), NPA requests that HCFA modify §460.154(k) to state that the enrollment agreement must contain descriptions of both the services available through the PACE provider, as well as those services not available. See 64 Fed. Reg. 66234, 66293; 42 C.F.R. §460.154(k). Second, NPA requests that HCFA modify §460.154(t) to state that the enrollment agreement must contain “[T]he signature of the applicant or his or her designated representative, and the date.” See 64 Fed. Reg. 66234, 66293; 42 C.F.R. §460.154(t).

§460.160: Continuation of enrollment.

NPA concurs with the requirements set forth in this section. See 64 Fed. Reg. 66234, 66294; 42 C.F.R. §460.160. However, with respect to HCFA’s request for comments regarding whether it should promulgate a process by which the annual recertification process can be reinitiated for a particular participant once a waiver of recertification for such participant has been granted, see 64 Fed. Reg. 66234, 66263, NPA believes that states will waive their right to annual recertification only in those instances where the possibility for improvement or significant change in condition is extremely remote. Consequently, NPA does not believe it is necessary to provide a mechanism to reinitiate the recertification process. NPA also notes that, although the regulation does not provide for such mechanism, it also does not explicitly preclude a state from reinitiating the recertification process.

Further, HCFA has requested comment regarding whether the State administering agency, the PACE organization or both should have responsibility for determining whether an individual is deemed eligible for PACE. See 64 Fed. Reg. 66234, 66263. NPA agrees with HCFA that the determination should be made by the State administering agency, which may solicit input from the PACE organization. See 64 Fed. Reg. 66234, 66294; 42 C.F.R. §460.160(b). This approach is consistent with NPA’s strong belief that the State is the appropriate decisionmaker with regard to level of care determinations. Further, NPA agrees that the period of deemed eligibility should continue for twelve (12) months until the next annual recertification is due. Id.

§470.170: Reinstatement in PACE.

This section provides that, contrary to the PACE Protocol, a PACE participant previously disenrolled may be eligible for unlimited reinstatement in the PACE program. See 64 Fed. Reg. 66234, 66295; 42 C.F.R. §460.170; see also PACE Protocol, Part
HCFA provides a rationale in the preamble for modifying the Protocol provision. See Fed. Reg. 66234, 66265. In particular, HCFA presents a scenario in which a PACE participant voluntarily disenrolls from the PACE organization because he or she experiences a change in their living arrangement which removes them from the PACE organization’s service area. Id. Subsequently, upon his or her return to the PACE organization’s service area, the participant desires to reenroll in the PACE program.

While this scenario serves as a reasonable basis for reinstatement, NPA offers an alternative scenario, which was considered when the PACE Protocol’s limitation was initially drafted. Specifically, we are concerned that unlimited reinstatement will result in situations under which PACE participants who pay a monthly premium and/or significant cost shares will voluntarily disenroll and reenroll in PACE based on their service needs in a particular month. Under such circumstance, participants will enroll in PACE programs during months of high utilization and cost, thereby disadvantaging the PACE organization in an inappropriate manner. Accordingly, NPA requests that HCFA reinstate the limitation contained in the PACE Protocol, or, alternatively, that the PACE organization be granted discretion to determine whether to reinstate a participant multiple times. Such determinations will be based upon the unique circumstances of the previous disenrollment, which circumstances will be identified in established policies and procedures prior to implementation of the PACE program.

§460.210: Medical Records.

NPA, in general, agrees with the medical records requirements set forth in this provision. However, NPA disagrees with the requirement including accident and incident reports within the medical record. See 64 Fed. Reg. 66234, 66297; 42 C.F.R. §460.210(b)(13). Although changes in a participant’s health status resulting from an accident or other incident would be noted in the medical record, as well as in an assessment of the participant’s resulting health care needs and modifications to his/her care plan, NPA does not believe that it is appropriate to include in the medical records the formal documents evidencing such accidents and/or incidents. Accordingly, NPA requests that HCFA delete such reports from the list of items to be included in the medical record.

HCFA has requested comment regarding whether the regulations should include a specific timeframe for the transfer of participant medical record information. See 64 Fed. Reg. 66234, 66270. NPA does not believe that any timeframe could possibly accommodate the range of circumstances under which participant medical record information might be transferred. Further, when contracting with other certified, licensed Medicare and Medicaid providers, PACE organizations become subject to the requirements pertaining to the transfer of medical record information applicable to such other providers. Accordingly, NPA recommends against the imposition of a timeframe for transfer.
**Additional Comments.**

Although the regulation does not specifically promulgate rules directing the involvement of State Agencies on Aging with PACE programs, NPA would like to comment on HCFA’s direction in the regulation’s preamble instructing the State agency administering PACE to “regularly consult with the State Agency on Aging in overseeing the operation of the PACE program.” See 64 Fed. Reg. 66234, 66235. We support HCFA’s recognition of the importance of State Agencies on Aging in serving frail elderly populations such as those enrolled in PACE. However, we encourage HCFA to acknowledge that States should display great variation in such involvement, depending on each State’s individual circumstances. For example, in States where the Agency on Aging performs a strong role, we share HCFA’s perspective regarding the Agency’s high involvement with the PACE program and expect that such consultations will occur as a matter of course. In other States, however, linkages between the State Medicaid agency and the State Agency on Aging are weak and a strong involvement would be improbable and inadvisable. Recognizing the unique relationships that exist in each State, we oppose a blanket requirement with respect to the degree and type of involvement between the State Agency on Aging and the PACE program.

NPA would also like to take the opportunity to respond to HCFA’s request for comments regarding the role of the State Long Term Care Ombudsman Program in promoting the rights of PACE participants and in monitoring the quality of care provided by PACE organizations. See 64 Fed. Reg. 66234, 66252-66253. NPA welcomes the involvement of State ombudsmen in assuring the quality of care provided by PACE organizations. However, we strongly encourage HCFA to permit each State to decide, in its sole discretion, whether to involve its ombudsman program staff in assisting PACE participants. If a State so chooses, we further encourage the State to allocate funding sufficient to deter the dilution of the staff’s efforts to monitor the quality of services provided in nursing homes.

Further, because of the substantial differences between the PACE program and nursing home care, State Long Term Care Ombudsman Program staff are unlikely to be knowledgeable about the PACE model. Accordingly, NPA strongly advocates that, in those States that choose to involve their ombudsman program with the PACE program, the ombudsman staff be provided with the necessary education regarding such differences and the appropriate manner by which the differences can be managed. To the extent it is appropriate, certain staff of NPA and/or the individual PACE organizations would be available to participate in such educational activities. Lastly, to ensure proper education and implementation, NPA encourages the State to monitor and oversee the process, utilizing techniques such as the development of defined protocols and the establishment of audit procedures to assess the effectiveness and efficiency of such protocols, in particular, as well as the process, in general.
NPA appreciates the opportunity to comment on HCFA’s proposed regulation with respect to the PACE provider programs. The comments included herein reflect the unanimous opinion and consent of the Board of Directors of the National PACE Association, as well as the input of NPA’s membership organizations. Accordingly, NPA respectively submits this letter in response to HCFA’s solicitation for comment with regard to the proposed regulation implementing PACE programs under the Medicare and Medicaid programs.

Sincerely,

Judith Baskins
President, National PACE Association
ATTACHMENT 1

SITES ELIGIBLE FOR “SET ASIDE” AS PROPOSED ON PP. 23-24

PACE demonstration programs:

AltaMed SeniorBuena Care, Los Angeles, CA
Alexian Brothers Community Services, Chattanooga, TN
Bien vivir Senior Health Services, El Paso, TX
Center for Elders Independence, Oakland, CA
Center for Senior Independence, Detroit, MI
Community Care for the Elderly, Milwaukee, WI
Comprehensive Care Management, Bronx, NY
Concordia Care, Cleveland Heights, OH
Eddy SeniorCare, Schenectady, NY
Elder Care Options, Madison, WI
Elder Service Plan at Fallon, Worcester, MA
Elder Service Plan – East Boston Neighborhood Health Center, East Boston, MA
Elder Service Plan of Harbor Health Services, Inc., Dorchester, MA
Elder Service Plan of Mutual Health Care, Dorchester, MA
Elder Service Plan of the Cambridge Hospital, Cambridge, MA
Hopkins ElderPlus, Baltimore, MD
Independent Living for Seniors, Rochester, NY
Independent Living Services, Syracuse, NY
On Lok Senior Health Services, San Francisco, CA
Palmetto SeniorCare, Columbia, SC
Providence ElderPlace in Portland, Portland, OR
Providence ElderPlace -- Seattle, Seattle, WA
Sutter SeniorCare, Sacramento, CA
Total Longterm Care, Denver, CO
TriHealth SeniorLink, Cincinnati, OH

Organization which submitted waiver application prior to publication of regulation:
Alexian Brothers Community Services of St. Louis, St. Louis, MO

Operational Pre-PACE programs:

Elder Service Plan of the North Shore, Lynn, MA
LIFE -- Pittsburgh, Inc., Pittsburgh, PA
LIFE -- St. Agnes, Philadelphia, PA
LIFE -- University of Pennsylvania School of Nursing, Philadelphia, PA
PACE Hawaii at Maluhia, Honolulu, HI
REACH, Chicago, IL
Sentara Senior Community Care, Virginia Beach, VA
St. Joseph’s Senior Care, Albuquerque, NM