September 11, 2017

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS—1676—P
P.O. Box 8016
Baltimore, MD  21244-8013

**RE: CMS—1676—P; Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program, (Vol. 82, No. 139) July 21, 2017**

Dear Ms. Verma:

On behalf of the membership of the National PACE Association (NPA) which includes 118 PACE organizations and a significant number of additional provider organizations pursuing PACE development, NPA appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services’ (CMS) request for information on CMS flexibilities and efficiencies included in the proposed physician fee schedule rule. We offer the following suggestions for improvements and simplifications to current regulatory requirements and restrictions that we believe would expand the availability of Programs of All-inclusive Care for the Elderly (PACE) and improve operational flexibility without compromising the person-centeredness and quality of care for which PACE programs are well known.

- **Enhance opportunities for flexibility and efficiency in PACE by releasing the Final PACE Rule.** On August 16, 2016, CMS issued a proposed rule for PACE. When finalized, it will be well over ten years since substantial changes were made to PACE regulatory requirements released in December 2006. We appreciate CMS’ efforts to update PACE regulatory requirements and strongly encourage the release of the final PACE rule as soon as possible. NPA and its members are hopeful that CMS will issue a final rule that takes into account the full range of comments on the proposed rule submitted by NPA (attached).

- **Improve care and control costs for new high-need, high-cost populations by moving forward with PACE-like pilots authorized under the PACE Innovation Act of 2015.** Currently, enrollment in PACE
is limited to individuals who are a minimum 55 years of age and meet their state’s eligibility criteria for nursing home level of care. With passage of the PACE Innovation Act, CMS has authority to develop pilots using the PACE model as a framework to serve beneficiaries under the age of 55 who are eligible for nursing home care, as well as other populations who may or may not be nursing home eligible—these populations include but are not limited to individuals with physical disabilities, intellectual and developmental disabilities, severe and persistent mental illness, and other medically complex populations at risk for nursing home care, among others. We appreciate the efforts that CMS has made thus far in releasing requests for information to implement one or more PACE-like pilot programs and strongly encourage CMS to release requests for proposals in the very near future as the next step towards their implementation.

- We would like to highlight several steps that we believe would increase Medicare and Medicaid beneficiaries’ access to patient-centered, high quality care in PACE, consistent with CMS’ intent behind the RFI (CMS—1676—P) to increase quality of care and make the health care system more effective, less complex and more accessible. In the case of PACE participants, all of whom are eligible for nursing home level of care, these are high-cost, high-need beneficiaries in need of intensive, highly coordinated medical care, and long term services and supports. With the objective of expediting access to PACE, we ask CMS to consider the following:

  - To enhance access to PACE for Medicare-only beneficiaries, allow PACE organizations to exercise BIPA 903 waiver authority to provide them with greater flexibility in establishing premiums for Medicare-only PACE participants. Currently, PACE participants who are not eligible for Medicaid must pay privately for PACE services otherwise covered by Medicaid for dual-eligible participants. Currently, under §460.186 of the PACE regulation, PACE organizations must set private-pay premiums at amounts equivalent to their state’s Medicaid capitation rate. With few exceptions, PACE Medicaid rates for dual-eligible beneficiaries are not individually adjusted for risk or need. We request that PACE organizations be able to utilize PACE’s BIPA 903 waiver process to request greater flexibility in how private pay premiums are set reflecting consumers’ interest in differentiated rates based on the range of care needs within the nursing home level of care population.

  - Allow beneficiaries to enroll in PACE mid-month rather than limiting effective dates of enrollment to the first day of the month. Beneficiaries considering PACE enrollment are often in immediate need of long term services and support and may not be able to wait days or even weeks before they and/or their family members must make decisions about their care. We believe that allowing eligible beneficiaries to access PACE services throughout the month may deter nursing home placements for those individuals in immediate need of services.

  - To facilitate PACE organizations’ ability to open or expand as expeditiously as possible, allow for entities to submit provider applications throughout the year, rather than limiting application submissions to just once per quarter. Prospective and existing PACE organizations must coordinate the PACE initial and service area expansion (SAE) application processes with involvement from their state administering agencies, and, for new PACE organizations as well as existing PACE organizations seeking to open new PACE centers, the construction or renovation
of these centers. Due to the complexity of this, it is possible that unforeseen circumstances may cause an entity’s application submission to be delayed with the next possible application timeframe months away. This can result in delays to beneficiaries’ access to PACE services and entities having to incur substantial expenses absent any revenue, a scenario related to the fact that a PACE center may be ready but cannot be utilized until the application is approved and enrollment begins.

- For reasons consistent with those outlined in the previous bullet, we ask that CMS eliminate the application requirement for existing PACE organizations seeking to open new PACE centers in existing service areas and, alternatively, allow them to do so after providing CMS with appropriate notice. This situation involves only experienced PACE organizations that have demonstrated their ability to comply with PACE requirements. A recommended process for providing CMS notification of a new PACE center within a PACE organization’s existing service area is included in NPA’s comment on the proposed PACE rule (pp. 3-4).

- **Consider modifications to the Medicare provider and supplier enrollment rule.** On November 15, 2016, CMS published a final rule on Medicare Advantage provider enrollment in which CMS requires that all providers or suppliers who are eligible to enroll in Medicare be enrolled and in an approved status by January 1, 2019 to provide care to PACE participants. This requirement applies to staff of PACE organizations as well as to staff of entities with which PACE organizations contract to provide services to their participants. NPA is concerned about both the administrative burden this will create for PACE organizations and PACE organizations’ ability to achieve 100% Medicare enrollment among eligible staff of contracted entities.

With respect to employed and contracted PACE organization staff, they may not be enrolled in Medicare because they provide services exclusively to PACE participants and are not enrolled in Medicare to submit fee-for-service claims. We believe Medicare enrollment of PACE staff is not necessary to ensure beneficiary protection or protect program integrity. The PACE organization itself is approved as a Medicare provider through CMS’ application process and, as a provider entity, has specific responsibilities to ensure the health and safety of PACE program participants, as well as program integrity, through employment screening and continued oversight and training of PACE staff. PACE programs furnish their participants the care they need mostly through health care professionals who are employed by the PACE program and with whom PACE participants interact regularly. There is no incentive to over-prescribe items and services, rather there is every incentive to employ and contract with staff who are specifically trained to care for this vulnerable population and who meet rigorous standards for quality and integrity established under existing regulations in 42 CFR Part 460 and subregulatory guidance.

With respect to requiring Medicare enrollment for eligible staff of entities with which PACE organizations contract, these staff may not already be required to enroll in Medicare. As an example, our understanding is that physical therapists who work for home health agencies, hospitals or skilled nursing facilities and do not bill Medicare directly are not currently required to be enrolled in Medicare. If all eligible practitioners were required to be enrolled in fee-for-service Medicare, we would not expect this requirement to be difficult to fulfill. To the extent this is not the case,
however, we are concerned about PACE organizations’ ability to require enrollment through its contracts as these contracts often contribute a small proportion of patients to contracted entities’ caseloads. As a result, we recommend that an all-inclusive requirement for provider and supplier enrollment not be imposed on PACE until a comparable requirement is applied more broadly in fee-for-service Medicare.

• **Continue efforts to improve CMS’ audit process for PACE.** In 2017, CMS has implemented a new audit process for PACE which is substantially different from the audit processes used in prior years and, to our understanding, incorporates features of Medicare Advantage (MA) audits. Currently substantial resources are being expended by PACE organizations to comply with updated audit requirements including extensive requirements for comprehensive data universes related to service delivery requests, appeals, grievances, personnel, participant medical records, quality initiatives and after-hours calls. While a variant of the MA audit process may be appropriate for certain aspects of the PACE program, we are concerned that the new audit process may not appropriately recognize the differences between PACE and MA organizations regarding their structure, data systems and provider responsibilities and capacities. At this juncture, we believe it would be productive to schedule a meeting involving CMS and NPA staff and representatives from several PACE organizations that have undergone an audit using the new protocol. To date, NPA has shared some concerns and questions related to the audit and underlying policy guidances in writing and look forward to CMS’ responses to these. We believe it would be productive to engage with CMS in an interactive discussion to discuss PACE organizations’ experience under the new audit process thus far and considerations for how it might be improved moving forward drawing upon the experiences of both CMS and state auditors and PACE organizations to date.

We very much appreciate CMS’ consideration of our comments and are hopeful of the opportunity to work with CMS to move these recommendations forward. If you have questions, please contact me or Chris van Reenen, NPA’s vice president for regulatory affairs, at (703) 535-1565, or shawnb@npaonline.org or chrisvr@npaonline.org.

Sincerely,

Shawn M. Bloom
President and CEO