January 10, 2018

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS—4182—P
P.O. Box 8013
Baltimore, MD 21244-8013
http://www.regulations.gov

RE: CMS-4182-P—Medicare Program; Contract Year (CY) 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program

The National PACE Association (NPA) appreciates the opportunity to respond to the Centers for Medicare and Medicaid Services (CMS) request for comment on proposed CY 2019 policy and technical changes contained in the above referenced notice of proposed rulemaking published in the Federal Register on November 28, 2017.

NPA is a national organization representing 119 operating PACE organizations in 30 states, and more than 50 additional entities pursuing PACE development and supportive of PACE. PACE organizations serve among the most vulnerable of Medicare and Medicaid populations—frail, older adults who are State certified as requiring a nursing home level of care. Fully integrated PACE organizations provide program participants with all needed medical and supportive services, including the entire continuum of Medicare- and Medicaid-covered items and services, with the objective of maintaining the independence of program participants in their homes and communities for as long as possible. The hallmark of the PACE model is the PACE interdisciplinary team (IDT) made up largely of PACE organization staff. The PACE IDT is made up of primary care providers, nurses, social workers, physical and occupational therapists, recreational therapists or activity coordinators, dietitians, PACE center managers, home care coordinators, and drivers and personal care aides or their representatives. Individual PACE organizations may include other disciplines as needed, e.g., pharmacists and behavioral health specialists. These individuals assess participants' care needs, and develop and implement comprehensive, fully integrated care plans providing many services directly in the PACE center and participants' homes.

NPA's comments are organized in the order the proposed changes appear in the November 28, 2017 Federal Register notice:

1. Implementation of the Comprehensive Addiction and Recovery Act (CARA) Provisions (pp. 56340-56360, pp. 56510-56513)

Currently, PACE organizations are waived of requirements for drug utilization management, quality assurance, and medication therapy management programs under §423.153 with the understanding that they are either in conflict with or duplicative of PACE requirements, or because the waiver improves PACE organizations' coordination of PACE and Part D benefits. The waivers of §423.153 for PACE organizations recognize that, in contrast to insurer-based Medicare Advantage (MA) and Part D Prescription Drug Plans, PACE organizations are provider-based and, as such, relate to their enrollees and are able to manage their drug utilization very differently from other Part D plan sponsors. Generally, PACE participants' prescribers are employed by their PACE organizations, which monitor each participant's care, including use of prescription drugs, directly and on a frequent basis. If participants' prescribers are not employed by the PACE organizations themselves, e.g. in cases where a PACE organization utilizes contracted community-based primary care physicians, PACE programs utilize relatively small networks of contracted physicians who interact on a regular basis with participants' interdisciplinary teams.

NPA asks CMS to confirm that nothing in the proposed rule impacts PACE organizations' waivers of Part D requirements in §423.153. In addition, we request that existing waivers of §423.153 be extended to include §423.153(f) unless such a waiver is not needed due to the voluntary nature of the drug management program.

Limitation on the Special Enrollment Period (SEP) for LIS Beneficiaries with an At-Risk Status (pp. 56351-56352, p. 56507)**.** NPA wants to confirm that any limitations on Part D low-income subsidy eligible individuals' SEP resulting from the proposed modification to §423.38(c)(4) would not impact the ability of such individuals, assuming they meet PACE eligibility requirements, to disenroll from a PDP or MA-PD at any time throughout the year to enroll in PACE using the PACE SEP. Because of the highly coordinated care system in PACE, disenrollment from a PDP/MA-PD would not be a means by which a PACE-eligible beneficiary could circumvent appropriate oversight of use of opioids or other frequently abused drugs. Alternatively, enrollment in PACE would be an effective means by which to manage drug utilization for an at-risk population. In addition, we would appreciate CMS' confirmation that the proposed modification to Part D low-income subsidy eligible individuals' SEP would not prevent beneficiaries who disenroll from PACE from enrolling into a MA-PD or PDP at any time throughout the year.

2. Coordination of Enrollment and Disenrollment Through MA Organizations (MAO) and Effective Dates of Coverage and Change of Coverage (pp. 56365-56368; pp. 56494-56495)

In response to CMS' proposal to allow default enrollment or seamless conversion for newly-eligible Medicare beneficiaries into MA dual eligible special needs plans (D-SNPs) under certain circumstances, NPA supports CMS' efforts to encourage dual eligible beneficiaries' enrollment in plans that integrate Medicare and Medicaid benefits. We believe, however, that it is crucial and in a beneficiary's best interest to be fully informed of the entire range of options that are available to him/her at critical decision points. Therefore, while we support CMS' proposed default enrollment of certain individuals into D-SNPs, it is essential that the notice required under proposed §422.66(c)(2)(iv) include all key

information necessary for the beneficiary to make an informed decision. This includes information on the availability of alternative plans which may, depending on the individual's geographic location and level of care, include PACE. Thus, in addition to making individuals aware of alternative choices including MA and fee-for-service, the notice required under proposed §422.66(c)(2)(iv) should specifically reference PACE and provide guidance on how to access detailed information about PACE, its eligibility requirements and whether PACE is an option where the individual lives. It is also important to inform individuals about the implications of plan selection for their ability to obtain Medigap on a guaranteed issue basis should they decide to shift later to fee-for-service Medicare.

In addition, to assure that individuals receive consistent information on their options, we recommend that CMS require that any additional outreach materials provided by the MAOs into which beneficiaries may be default-enrolled provide information about alternative options including PACE.

With respect to CMS' proposed "opt-in" election process that would be available to all MA organizations for MA enrollments of their commercial, Medicaid or other non-Medicare members, consistent with NPA's comment above on default enrollment, we recommend that during the opt-in enrollment process MAOs be required to provide notice to their non-Medicare health plan members and that this notice inform members of their choices as newly eligible Medicare beneficiaries, i.e., fee-for-service Medicare, MA plans including the one affiliated with the plan in which they are currently enrolled, and PACE. Consistent with our recommendation for the contents of the notice required under §422.66(c)(2)(iv), the information about PACE should provide guidance on how to access detailed information about PACE, its eligibility requirements and whether PACE is an option where the individual lives. It is also important to inform individuals about the implications of plan selection for their ability to obtain Medigap on a guaranteed issue basis should they decide to shift later to fee-for-service Medicare.

3. Passive Enrollment Flexibilities to Protect Continuity of Integrated Care for Dually Eligible Beneficiaries (pp. 56369-56371, p. 56493)

Although NPA supports CMS' efforts to encourage dual eligible beneficiaries' enrollment in plans that integrate Medicare and Medicaid benefits, it is always in a beneficiary's best interest to be fully informed of the entire range of options that are available to him/her at critical decision points. Consistent with this principle, NPA believes it is essential to inform impacted D-SNP enrollees of all their options prior to passive enrollment into another D-SNP. Thus, in the notice required by proposed §422.60(g)(4), the notice should make beneficiaries aware of the availability of both other MA plans and PACE. We ask that CMS require a reference to PACE in this notice with guidance on how to access detailed information about PACE, its eligibility requirements and whether PACE is an option where the individual lives. This recommendation is consistent with the notice provided to beneficiaries who have been passively enrolled into Medicare-Medicaid Plans in states where PACE exists.

4. Establishing Limitations for the Part D Special Election Period (SEP) for Dually Eligible Beneficiaries (pp. 56373-56375, pp. 56507-56508)

NPA seeks CMS' assurance that by limiting the SEPs for dually eligible and other low-income subsidy eligible beneficiaries as proposed, CMS will not in any way be limiting PACE-eligible Medicare beneficiaries' ability to enroll in a PACE organization continuously throughout the year. We believe continuous access to PACE supports CMS' interest in promoting beneficiaries' access to fully integrated,

coordinated Medicare and Medicaid benefits. Conversely, we want to assure that CMS' proposed changes would not limit the ability of a Medicare beneficiary disenrolling from PACE to access a PDP or MA-PD continuously throughout the year.

5. Medicare Advantage and Part D Prescription Drug Program Quality Rating System (pp. 56375-56407; pp. 56514-56520)

Because PACE organizations are not subject to the Star Ratings System, NPA wants to confirm that, if finalized, requirements in new §423.180-186 will be waived for PACE organizations.

6. Restoration of the Medicare Advantage Open Enrollment Period (pp. 56428-56429, pp. 56493-56495, pp. 56507-56508)

Consistent with comments provided above, with respect to the proposed restoration of the MA open enrollment period and other proposed changes to MA and PDP SEPs elsewhere in the proposed rule, NPA asks CMS to confirm that the PACE SEP will continue to allow MA and Part D enrollees to disenroll from an MA plan, an MA-PD or a standalone PDP at any time throughout the year to enroll in PACE. Conversely, PACE participants may disenroll at any time throughout the year and access MA, MA-PD and PDP options.

7. Preclusion List – Part D Provisions (pp. 56441-56447, pp. 56509-56510)

Referring to CMS' Contract Year 2018 Medicare Part D Application for New PACE Organizations (p. 10), §423.120(c) is among the sections of the Part D regulation that are listed as waived for PACE organizations. This said, NPA asks if CMS intends to impose requirements in proposed §423.120(c)(5) and §423.120(c)(6) on PACE organizations.

If requirements under proposed §423.120(c)(5) for an active and valid NPI on all pharmacy claims apply to PACE organizations, we request a waiver for PACE organizations of the requirement in proposed §423.120(c)(5)(ii) for Part D sponsors to communicate at point-of-sale if an NPI is active and valid. Such a waiver would be consistent with CMS' recognition of differences in how Part D may be implemented by PACE organizations and the way PACE organizations interact with their contracted pharmacies to obtain Part D drugs on behalf of their participants.

If the Part D preclusion list requirements in proposed §423.120(c)(6) are applied to PACE organizations, we request that the effective date for the new preclusion list requirements in proposed §423.120(c)(6) provide PACE organizations with a minimum of one year subsequent to publication of the final rule to come into compliance**.** Further, we request that CMS provide as many operational details about how the preclusion rule will be accessed, updated, etc. as early in that year as possible to give PACE organizations and other impacted entities with sufficient time to implement new processes.

Regarding the requirements to provide a beneficiary with a provisional supply of drugs and notice in situations where a prescription is prescribed by a prescriber on the preclusion list, we request CMS to consider what would happen to a PACE participant in this situation. Such a prescriber would either be a primary care physician/nurse practitioner/physician assistant employed by the PACE organization, or a contracted primary care provider or medical specialist. As such, once he/she appeared on the preclusion list, the PACE organization immediately would act to replace the precluded provider, thereby assuring

the continued availability of the prescribed medication as well as access to care. If the Part D preclusion list requirements in proposed §423.120(c)(6) are applied to PACE organizations, we ask CMS to consider differences between PACE organizations and traditional Part D plans in implementing the provisional supply and notice requirements in order to avoid confusion among PACE participants and their families.

Lastly, referring to proposed §423.120(c)(6)(iii), it is our understanding that Part D plan sponsors may not submit a PDE record to CMS if the prescriber is included on the preclusion list; however, sponsors are required to pay for provisional supplies of such drugs per proposed §423.120(c)(6)(iv). We ask CMS to consider conforming language in proposed §423.120(c)(6) allowing for submission of PDE for provisional drugs required under proposed §423.120(c)(6)(iv).

8. Preclusion List – Part C/Medicare Advantage Cost Plan and PACE Provisions (pp. 56447-56454, pp. 56526-56527)

NPA very much appreciates CMS' efforts to address NPA's and others' concerns related to the existing provider and supplier enrollment requirement and believes that the proposed preclusion list requirement will accomplish CMS' objective of ensuring that only qualified providers and suppliers provide services to Medicare beneficiaries in a significantly less burdensome way. Consistent with NPA's comments on the effective date for preclusion list requirements under Part D if applied to PACE organizations, we request that the effective date for preclusion list requirements under §460.40, §460.50 and §460.86 provide PACE organizations with a minimum of one year subsequent to publication of the final rule to come into compliance and that CMS provide as many operational details about how the preclusion rule will be accessed, updated, etc. as early in that year as possible to give PACE organizations and other impacted entities with sufficient time to implement new processes.

NPA has several additional questions and recommendations for which we would appreciate CMS' consideration and response:

a) What is the relationship between the OIG exclusion list and the CMS preclusion list? Would everyone on the OIG exclusion list also be included on the CMS preclusion list?

b) Because PACE organizations provide both Medicare and Medicaid covered services, we would like to clarify how the preclusion list requirement would apply to staff, and contracted individuals and entities who are not eligible to enroll in Medicare, e.g., nurses, recreational therapists, drivers, etc. We assume and request CMS' confirmation that these individuals and entities will not be vetted for inclusion on the Part C preclusion list and, therefore, it would not be necessary/productive to check these individuals/entities against the preclusion list.

c) We understand PACE organizations' responsibilities with respect to confirming that PACE organization staff (both employees and contracted staff), and entities and individuals with which PACE organizations contract directly are not on the OIG exclusion list or CMS' preclusion list. We seek clarification of CMS' expectations of PACE organizations with respect to employees of contracted (first tier, downstream and related) entities. Is CMS expecting PACE organizations to hold contracted entities responsible for confirming that their staff, whether employed or contracted, are not on the CMS preclusion list? We recommend that preclusion requirements not extend beyond those individuals and entities with whom PACE organizations contract

directly unless a similar requirement is implemented in fee-for-service Medicare such that hospitals, nursing homes, home health agencies, etc. are required to check their staff against the preclusion list. Our concern is that by imposing an additional contractual requirement on PACE organizations, their ability to secure contracts may be negatively impacted. We recommend that PACE organizations be required to check only the individual or entity with which it contracts against the preclusion list. Any requirement on PACE organizations for employees of contracted entities to be vetted against the CMS preclusion list should be delayed until such a requirement for these employees exists in fee-for-service at which time such a requirement would be universal and not applied distinctively by PACE (and MA) organizations.

d) Lastly, regarding the requirement to provide notice to PACE participants if a PACE organization receives a request for payment by an individual or entity that is excluded by the OIG or is included on the preclusion list, consistent with related comments in response to the Part D preclusion list requirement, we ask CMS to consider differences between PACE organizations and MA plans in implementing the notice requirement.

Thank you very much for your consideration of NPA's response to CMS' request for comment. If you have any questions regarding NPA's response, please direct them to Chris van Reenen, NPA's Vice President of Regulatory Affairs at chrisvr@npaonline.org or (703) 535-1568.

Sincerely,

Shawn M. Bloom
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