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October 17, 2016

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Mr. Slavitt:

AMGA welcomes the opportunity to comment on the "Medicare and Medicaid Programs: Programs of All-Inclusive Care for the Elderly (PACE) (CMS-4168-P)." AMGA, founded in 1950, represents more than 450 multi-specialty medical groups and integrated delivery systems representing about 177,000 physicians who care for one-in-three Americans. In addition to PACE, our member medical groups participate in fee-for-service and Medicare Advantage (MA), the two, soon to be three, bundled payment demonstrations, as well as in several other CMS demonstrations including the Pioneer and Next Generation Accountable Care Organization (ACO) demonstrations. Therefore, AMGA has a strong interest in how seeing the PACE program grow and succeed.

AMGA's comments are in order of how these subtopics appear in the proposed rule.

PACE Monitoring and Oversight

CMS is proposing PACE organizations (POs) develop oversight requirements that would monitor and audit their organization for compliance with regulations. CMS is also proposing to require each PO to have measures that prevent, detect and correct non-compliance with CMS program requirements, as well as measures that prevent, detect and correct fraud waste and abuse. Due in part to these proposals, CMS is proposing to reduce the number or frequency of on-site compliance visits after the three-year trial period by using a risk assessment to select which POs will be audited annually. AMGA supports these proposals.

Part D Prescription Drugs

CMS is proposing to require POs "offering qualified prescription drug coverage and meeting the definition of a Part D plan sponsor must abide by all applicable Part D program requirements" unless a specific requirement has been waived. This proposal clarifies the 2006 final PACE rule that indicated Part D prescription requirements would apply to POs that elect to provide qualified Part D prescription drug coverage. AMGA supports this clarification. Though unmentioned, PACE participants are required to enroll in the PO's Part D plan. Since CMS is interested in aligning benefits across programs, PACE participants also ought to have a choice of Part D plans.

PACE Personnel Qualifications

Currently CMS requires personnel who have direct participant contact must have at least one year of



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experience with a frail or elderly population. CMS is proposing to allow hiring based on all other qualification requirements except the one year requirement. However, upon hiring a new employee without the experience, the PO will be required to appropriately train the new employee using industry standards. This proposal, CMS states, "would afford POs the flexibility to hire an otherwise qualified individual with less than 1 year of experience working with the frail or elderly population." CMS also proposes to no longer require the PO to have their competency evaluation programs pre-approved by CMS. AMGA supports these proposals.

PACE Program Integrity

CMS is proposing to enable POs to make a determination as to whether an employee's contact with an PO participant would pose a potential risk because the employee had been convicted of one or more criminal offenses related to physical, sexual, drug or alcohol abuse or use. "A PO must not employ individuals or contract with organizations or individuals," CMS states, "who have been found guilty of abusing, neglecting or mistreating individuals by a court of law or who have had a finding entered into the state nurse aide registry concerning abuse, neglect, mistreatment of residents, or misappropriation of their property." CMS is making this proposal because, the agency states, "we do not want to foreclose POs from employing or contracting with qualified individuals or organizations that would pose no harm to participants despite past convictions." CMS requests comments on whether the agency should restrict hiring with respect to certain criminal justice histories that can include those with current restraining orders against them.

AMGA appreciates current related PACE program rules may be, as the agency states, "over broad" and the agency's concern not to "limit POs' ability to hire or contract with qualified individuals." That said, elder abuse is a serious, pervasive problem. For example, in a study titled, "Prevalence and Correlates of Emotional, Physical, Sexual, and Financial Abuse and Potential Neglect in the United States: The National Elder Mistreatment Study," published in February 2010 issue of the American Journal of Public Health, researchers found one in 10 respondents reported emotional, physical or sexual mistreatment in the past year. In "Elder Abuse: Disparities Between Older People's Disclosure of Abuse, Evident Signs of Abuse, and High Risk of Abuse," published in the Journal of American Geriatrics Society in June 2007, found 21 percent of 730 hospitalized patients 70 years or older were identified with evident signs of abuse and more than 70 percent of those who disclosed abuse were identified with evident signs of abuse particularly physical and sexual abuse. Because of such high prevalence, AMGA strongly believes CMS should err on the side of caution. For example, individuals with current restraining orders against them are not likely to be ideal PO employees or contractors. Since it is highly unlikely CMS can account for or identify a list of all unemployable "criminal justice histories," the agency could consider requiring the PO to psychologically screen prospective employees or contractors with a criminal history. For example, the agency could recommend or encourage POs to employ the Minnesota Multiphasic Personality Inventory or the Millon Clinical Inventory that attempt to identify psychological pathology or personality disorders, not for the purpose of making hiring decisions but to generate further employment screening. Although not fool proof this step would provide addition assurance an appropriate hiring decision was made.

PACE Marketing

Existing CMS regulations require that only PO employees market the PACE program because, CMS states, the program has substantially different rules and because of the vulnerability of the population served by the PACE program. CMS does realize some POs currently use independent agents and brokers to market their services. CMS is therefore proposing to remove the word “agent” such that POs are prohibited from using such non-employee agents for marketing purposes. If stakeholders believe the proposed prohibition is not appropriate, CMS requests stakeholders cite specific reasons for allowing the use of third party agents and explain how POs will ensure third party agents will provide prospective PACE enrollees accurate information. CMS is also proposing to remove the requirement that POs establish, implement, and maintain a documented marketing plan.

AMGA well recognizes the frailty of the PACE population and their vulnerabilities, recognizes the agency's concern agents may not, or do not, “fully understand” the program and the desire to avoid “enrollment numbers . . . becoming the primary motivation when marketing PACE.” Despite the fact the program was authorized in 1997, according to the National PACE Association (NPA), there are PACE programs in just 31 states providing care to approximately 35,000 Medicare (and Medicaid) participants.

According to a 2014 Assistant Secretary for Planning and Evaluation (ASPE)-commissioned Mathematica study titled, “Evaluating PACE: A Review of the Literature,” care quality and care management under PACE is considered sound. For example, the program improves certain aspects of care quality such as pain and reduces mortality risk. For these reasons and others, including a rapidly growing Medicare population over age 80, CMS should work aggressively to market more successfully the PACE program.

PACE Center Operation and Service Requirements

CMS notes the agency has received requests to “provide greater flexibility with respect to PACE center operation and service requirements.” Therefore, CMS is inviting “public comment on ways to revise the current regulatory requirements to allow greater flexibility with regard to the settings in which IDT (Inter-Disciplinary Team) members provide PACE services.” The agency will use this information to inform “future PACE rule making concerning how to allow greater flexibility with regard to setting in which IDT members provider PACE services.”⁸¹ AMGA supports the agency's intent to allow “greater flexibility” since CMS recognizes the “time required to establish a PACE center can be significant and as well. . . inhibit expansion of existing programs.” Up front capital costs to bring a PACE program to market can be as high as \$5 million according to industry estimates. AMGA encourages CMS to consider alternative settings for the delivery of PO services such as senior centers, adult day health centers, church programming facilities, fraternal organizational facilities and recreational facilities such as YMCAs.

PACE Interdisciplinary Team

CMS is proposing “that a PO be permitted to have one individual fulfill a maximum of two separate roles on an [eleven member] IDT when the individual meets applicable state licensure requirements.” CMS is also proposing to allow primary medical care be furnished by someone other than a primary care physician on the IDT, such as a Nurse Practitioner (NP), a Physician Assistant (PA) (consistent with state licensure requirements) or a community based physician to “reduce the burden on the POs without compromising care.”

Concerning the proposal to allow one individual to fulfill two IDT roles, AMGA supports the agency's interest in providing "greater flexibility for POs." Since CMS recognizes PACE participation can, in some instances, require the participant to stop seeking care from their current provider, allowing other community based physician to participate on the IDT is altogether sensible.

Plan of Care

CMS is proposing to change the requirement that a plan of care be developed promptly to "within 30 days of the date of enrollment." CMS also proposes three new requirements: the plan of care "utilize the most appropriate interventions for each of the participant's care needs;" "the plan of care identify each intervention and how it will be implemented;" and, "the plan of care identify how each intervention will be evaluated to determine progress in reaching specified goals and desired outcomes." AMGA agrees with these proposed provisions particularly since the average PACE participant, according to the NPA is in their latter 70s, has four to five chronic conditions, half have a dementia diagnosis and at least three activities of daily living (ADL) limitations.

Quality Assessment and Performance Assessment

CMS is proposing to require "A PO to have a written quality improvement plan that is collaborative and interdisciplinary in nature." AMGA agrees with the proposed change but recommends that it go further. As an example the agency identifies the goal of improving a PO's overall fall incident rate and that the plan of action involve soliciting recommendations from all PO providers including social workers, transportation providers and physical therapists. The proposals however makes no mention of evaluating the plan of action. Any written quality improvement plan should include ongoing evaluation steps the PO will take to measure improvement.

Medicaid Payment

At the conclusion of the "K. Subpart J – Payment, 1. Medicaid Payment," CMS states, "we are seeking input to determine whether or not there could be other rate setting methodologies for PACE that are more consistent and competitive with rate setting methodologies used for other programs that provide similar services to similar populations on a capitated basis."

In MedPAC's September 22 comment letter, the Commission noted the PACE program was excluded from ACA payment reform. Thus, MedPAC estimates PACE benchmarks are currently at approximately 120 percent of county fee-for-service (FFS) expenditures. The Commission stated further, "if PACE enrollees were in MA plans, or if PACE benchmarks were the same as those applicable to MA, the benchmarks would be at approximately 102 percent of FFS." The MedPAC letter goes on to note the Commission has recommended MA payment reforms under the ACA be applied to PACE and that PACE be equally eligible for quality bonus payments.

One of the proposed rule goals' is to align PACE with MA program rules. For example, CMS proposes MA requirements with respect to Part D prescription drug coverage be applied to POs and PO marketing requirements be consistent with MA. For the purposes of amending change of ownership notification rules, CMS explains in the proposed rule after May 19, 2015 POs are no longer required to be not-or-profit. More generally, CMS has been working to synchronize regulatory rules between and among Medicare programs. This



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is, for example, the ultimate objective of the Core Quality Measures Collaborative. CMS is also working to allow Medicare providers to simultaneously participate in multiple Medicare initiatives. For example, ACO program participants can participate in the Comprehensive Primary Care Plus (CPC+) demonstration, gain share in bundle payment demonstrations and CMS will allow MA or Medicare Part C participation to count toward Medicare Part B bonus payments under the Medicare Access and CHIP Reauthorization Act (MACRA) Alternative Payment Model (APM) pathway. In addition, there have been related efforts to better integrate Medicare programs, such as the Senate Finance Committee's December 2015 proposal to allow greater ESRD access to MA plans and adding the Medicare hospice benefit to MA. For these reasons and others one way to "set rates" that are "more consistent" with "other programs that provide similar services to similar populations on a capitated basis" would be to integrate PACE in MA, or allow MA plans to offer PACE-level care. Since PACE is Medicaid state option this would make moot the fact that 18 states currently do not offer PACE and would allow Medicare beneficiaries, that are not also Medicaid eligible, to participate in the PACE program.

Thank you for your consideration of our comments. If you have any questions please do not hesitate to contact David Introcaso, Ph.D., Senior Director of Regulatory and Public Policy, at dintrocaso@amga.org or at 703.842.0774.

Sincerely,

Donald W. Fisher, Ph.D.
President and CEO