January 12, 2018

Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-4182-P P.O. Box 8013 Baltimore, MD 21244-8013

RIN 0938-AT08

42 CFR Parts 405, 417, 422, 423, and 498 [CMS-4182-P]

Re: Medicare Program; Contract Year 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 Proposed Rule—Federal Register / Vol. 82, No. 227 / Thursday, November 28, 2017

The undersigned dental professional organizations welcome the proposed changes to the enrollment requirement for the Medicare Part C and Part D programs for providers who are not otherwise required to enroll and who do not submit claims to Medicare.

Specifically, the coalition supports the creation of the preclusion list as a substitute for the enrollment or opt-out requirement under Medicare Part D as discussed in paragraph 10. Preclusion List—Part D Provisions beginning on 56441 of the proposed rule and the proposed changes to 42 § 423.120(c) (6) as discussed on page 56444 (b) Replacement of Enrollment Requirement With Preclusion List Requirement: We are proposing to delete the current regulations that require prescribers to enroll in or opt out of Medicare for a pharmacy claim (or beneficiary request for reimbursement) for a Part D drug prescribed by a physician or eligible professional to be covered. We also propose to generally streamline the existing regulations because, given that we would no longer be requiring certain prescribers to enroll or opt out, we would no longer need an exception for "other authorized providers," as defined in § 423.100, for there would be no enrollment requirement from which to exempt them. Instead, we would require plan sponsors to reject claims for Part D drugs prescribed by prescribers on the preclusion list. We believe this latter approach would better facilitate our dual goals of reducing prescriber burden and protecting the Medicare program and its beneficiaries from prescribers who could present risks.

The coalition also supports the use of the preclusion list as identified in paragraph 11. Preclusion List—Part C/Medicare Advantage Cost Plan and PACE Provisions on page 56447 of the proposed rule and the establishment of a new § 422.204(c) that would require MA organizations to follow a documented process that ensures compliance with the preclusion list provisions in § 422.222 and deletes § 422.204(b)(5) because it applies to the Part C enrollment process, which will be eliminated and the revision of paragraph (b)(5) to address the preclusion list requirements could cause confusion, for paragraph (b) references providers and suppliers. The coalition would like to bring two other issues to CMS's attention. We are fully aware that section 6405 of the Patient Protection and Affordable Care Act (Public Law 111-148) requires physicians who order items or services under Medicare to enroll in Medicare or opt-out. However, in spite of the efforts of CMS and the coalition to publicize this to their members,

many dentists have chosen not to enroll in or opt-out. We believe some of the same reasons that caused dentists to fail to comply with the Part D rule apply to the ordering and referring rule. We also believe that applying the same preclusion list rules to items such as ordering laboratory tests or imaging services would prevent interruption in providing care to Medicare beneficiaries and will insure the integrity of CMS claims. The coalition urges CMS to pursue efforts to rewrite the current rule including seeking legislative relief from section 6405.

A related issue is the problem created with opting out of Medicare. Partially in response to the ordering and referring rule but most likely as a response to the Medicare Part D rule, some, but not many, dentists chose to opt-out. Unfortunately, there was an unintended consequence that if the dentist opts out they are no longer eligible to provide dental services for Medicare beneficiaries enrolled in Medicare Advantage (Medicare Part C). In addition, patients of those dentists are also precluded from filing a claim on their own behalf. Currently, a dentist who opts out is allowed to withdraw the opt-out affidavit within the first 90 days, thereafter they are opted out for two years. Many dentists did not learn of the impact on their participation in Medicare Part C plans until after the initial 90 day period had passed. Complicating the issue even more, CMS changed the rule so that effective June 16, 2015 unless the provider took affirmative action to withdraw the affidavit 30 days before the anniversary date, the enrollment automatically renewed for two more years.

Our organizations have received numerous calls from members who opted out in good faith trying to comply with the Medicare Part D rule only to learn later they were precluded for participating in Medicare Part C plans. Previously, the coalition has suggested that since CMS has changed the enforcement date at least five times since the initial rule was published, CMS should permit dentists who opted out a second opportunity to reconsider and allow them to withdraw their affidavit. It is our understanding that only a few thousand dentists have opted out. Based on this new regulation and change in enforcement, the coalition again urges CMS to allow the Medicare Contractors to contact each dentist who has opted out giving them the opportunity to withdraw the affidavit. We will gladly work with CMS to publicize this effort within our professional organizations.

The coalition would gladly meet with CMS to discuss our concerns. Please contact Dr. Frank Kyle in the ADA's Washington, DC Government Affairs office at 202-789-5175 or kylef@ada.org.

Sincerely,

American Dental Association
Academy of General Dentistry
American Academy of Oral and Maxillofacial Pathology
American Association of Endodontists
American Association of Oral and Maxillofacial Surgeons
American Association of Orthodontists
American Association of Women Dentists
American Dental Education Association
American Society of Dentist Anesthesiologists
National Dental Association