

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

Comments on the proposed changes to the enrollment requirements for Medicare Part C and Part D

The American Dental Association (ADA), the world's oldest and largest dental professional organization representing over 161,000 members in the United States, welcomes 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 ADA 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 ADA 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.

Comments on the proposed CMS rules implementing the Comprehensive Addiction and Recovery Act of 2016 pages 56339-56360 of the proposed rule.

The ADA supports CMS's goal of helping to address the opioid epidemic by providing a framework for Medicare Part D drug plan sponsors (both stand-alone and Medicare Advantage) to establish drug management programs for beneficiaries at risk for prescription drug abuse or misuse. ADA urges CMS to:

- **Include a dentist in case management team.** Require plan sponsors to include a dentist on the case management team, particularly when one or more prescribers is a dental prescriber, when clinical contact will be made with a dental practice, or when the case management team is considering or will consider whether a medication prescribed by a dental prescriber is appropriate for the beneficiary's condition.
- **Permit prescriber to agree, disagree, or neither agree nor disagree during clinical contact.** When a plan sponsor makes clinical contact to determine (1) whether a beneficiary is at risk or (2) whether to implement a claim edit or lock-in, the prescriber should be able to respond that he or she (1) agrees, (2), disagrees, or (3) neither agrees nor disagrees.
- **No telephone contact.** Prohibit plan sponsors from telephonic clinical contact with prescribers in order to avoid disrupting their practices and to reduce the risk of "phishing."
- **Safeguards to prevent "phishing."** Require plan sponsors policies and procedures for clinical contact to include secure identity verification safeguards to protect prescribers from "phishing" communications that attempt to trick prescribers into disclosing patient information.
- **Out of network prescribers.** Eliminate the requirement that a prescriber must be in-network if the plan sponsor imposes a limit on a beneficiary's access to coverage to a selected prescriber or prescribers.
- **Provider agreements.** Prohibit plan sponsors from including in their provider agreements any requirement that would require a prescriber to confirm in advance, or forego providing specific confirmation, if selected under a drug management program to serve an at-risk beneficiary.
- **Prior notice to prescriber.** Require plan sponsors to notify prescriber and obtain prescriber's prior written confirmation before informing a beneficiary of the selection of the provider in connection with a limitation on the beneficiary's access to coverage of frequently abused drugs.
- **Scope of practice.** Prohibit plan sponsors from selecting a prescriber in connection with a limitation on a beneficiary's access to coverage of frequently abused drugs, if the selection might involve a violation of applicable scope of practice limitations.

- **Group practice.** Permit group practices to designate one or more prescribers when a plan sponsor intends to limit, a beneficiary's access to coverage of frequently abused drugs to a selected prescriber or prescribers at a group practice, and permit the group practice to modify such designation from time to time. Require the plan sponsor to honor any such designation or modification. This should apply whether or not the prescribers at the group practice are all associated with the same single Tax Identification Number (TIN).
- **Second notice should list public health resources.** Require that the second beneficiary notice, as well as the first beneficiary notice, include a description of all state and federal public health resources that are designed to address prescription drug abuse to which the beneficiary has access, if the second notice tells the beneficiary that the plan sponsor intends to limit his or her access to coverage.

Additional Comments

The ADA 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 ADA, 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 ADA 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.


The ADA has 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 from participating in Medicare Part C plans. Previously, the ADA 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. The ADA urges CMS to allow the Medicare Contractors to contact each dentist who has opted out giving them the opportunity to withdraw the affidavit. The ADA will work with CMS to publicize this effort to within the profession.

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

Sincerely,

Handwritten signature of Joseph P. Crowley, D.D.S. in black ink.

Joseph P. Crowley, D.D.S.
President

Handwritten signature of Kathleen T. O'Loughlin in black ink.

Kathleen T. O'Loughlin, D.M.D., M.P.H.
Executive Director

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