

April 25, 2016

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-6058-P
P.O. Box 8013
Baltimore, MD 21244-8013.

RE: *Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process*, CMS-6058-P; RIN 0938-AS84, Federal Register Vol. 81, No. 40, March 1, 2016 p. 10720.

On behalf of our 159,000 members, we are pleased to offer these comments on the Centers for Medicare & Medicaid (CMS) in response to the proposed rule entitled *Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process* published in the Federal Register on March 1, 2016 (81 FR 10720; RIN 0938-AS84). As CMS explains in the summary, the proposed rule would require that to order, certify, refer or prescribe any Part A or Part B service, item or drug, a doctor must be enrolled in Medicare in an approved status or have validly opted out of the Medicare program. The proposed rule would also require Medicare, Medicaid, and Children's Health Insurance Program (CHIP) providers and suppliers to disclose certain current and previous affiliations with other providers and suppliers, and would provide CMS with additional authority to deny or revoke a provider's or supplier's Medicare enrollment.

The American Dental Association (ADA) is the world's oldest and largest dental professional organization, representing 159,000 dentists in the United States. The ADA is committed to the public's oral health, ethics, science and professional advancement and access to dental care for all Americans. ADA shares the concerns that CMS expresses concerning dishonest providers and suppliers who attempt to circumvent Medicare requirements through name and identity changes as well as through elaborate inter-provider relationships. ADA applauds CMS's goal to prevent fraud, waste and abuse. As taxpayers, dentists are also concerned about dishonest individuals and entities who attempt to circumvent Medicare requirements through name and identity changes as well as through elaborate inter-provider relationships. However, there appears to be little need for this requirement as it applies to dentists, and the administrative burden on dentists would be significant. ADA believes the proposed rule, as applied to dentists, will impose an unreasonable burden with negligible corresponding benefit to CMS, and asks CMS to exempt dentists from the scope of the proposed rule.

The ADA is on record as opposing the application of such requirements to dentists, in part because Medicare covers very few dental items and services, many (perhaps most) dentists have little incentive to enroll in Medicare other than in connection with CMS program integrity initiatives like the proposed rule. Moreover, dentists have historically faced, and will likely continue to face, unique burdens when attempting to enroll in Medicare. Even the

simplified CMS form 855O, which CMS developed to permit limited enrollment for purposes such as ordering covered clinical laboratory services, imaging services, and durable medical equipment, prosthetics and supplies (DMEPOS), has presented challenges to dentists. Enrollment difficulties could compromise patient safety and quality of care if Medicare beneficiaries are unable to obtain needed items and services due to a dentist's unenrolled status. Additionally financial hardships can result if beneficiaries, providers and suppliers are unable to obtain reimbursement where their claims are rejected because the ordering, referring or prescribing dentist was not properly enrolled or formally opted-out.

For a number of years, dentists who have attempted to enroll have faced what appears to be a lack of understanding about dentists and the dental profession. For example, both the Medicare provider enrollment form 855I and the simplified form 855O include itemized lists of medical specialties, but only two are applicable to the dental profession: "maxillofacial surgery" and "oral surgery (dentist only)." The ADA has been told to inform dentists who have questions about the lists to use those categories for enrollment purposes; however, most dentists would not recognize their practices as encompassed in those categories. "Oral and Maxillofacial Surgery" is one of the recognized specialties in dentistry, but unless the dentist practices that particular specialty he or she would not intuitively choose either of the listed categories when enrolling.

When a dentist who is a prosthodontist¹ tried to enroll using the form 855I and the "Undefined physician type" category and specified his specialty of prosthodontics, he was told by the Medicare contractor "There is no statutory or regulatory basis which permits a Prosthodontist to enroll or receive payment in the Medicare program." When this issue was raised with CMS, the reply was "Only Oral Surgeons (Dentist only) or Maxillofacial Surgeons can receive reimbursement for covered services to Medicare beneficiaries and should be completing the CMS-855I." This compounds the problem of dentists not being familiar with the term "oral surgeon" as pertaining to them, and Medicare contractors have also disallowed enrollment using that category. That leaves dentists in an untenable position. They are required to enroll, but are not allowed to enroll under any of the existing categories.

The definition of physician in the Social Security Act Section 1861(r)(2) states "...a doctor of dental surgery or of dental medicine who is legally authorized to practice dentistry by the State in which he performs such function and who is acting within the scope of his license when he performs such functions..." Dentists holding the Doctor of Dental Surgery (D.D.S.) or Doctor of Dental Medicine (D.M.D.) degrees and licensed to practice in their State should be recognized by both Medicare Contractors and by CMS as authorized to receive payments in Medicare and that applies to all the specialties of dentistry.

¹ Prosthodontics is the dental specialty pertaining to the diagnosis, treatment planning, rehabilitation and maintenance of the oral function, comfort, appearance and health of patients with clinical conditions associated with missing or deficient teeth and/or oral and maxillofacial tissues using biocompatible substitutes.

There are nine ADA recognized specialties in dentistry, plus general dentist, for a total of ten practice categories that should be available options on CMS enrollment forms. The specialties are: Dental Public Health, Endodontics, Oral and Maxillofacial Pathology, Oral and Maxillofacial Radiology, Oral and Maxillofacial Surgery, Orthodontics and Dentofacial Orthopedics, Pediatric Dentistry, Periodontics and Prosthodontics. Registration for the NPI includes all of the ADA recognized specialties, as well as a General Dentist category. Prior to implementation of the rule requiring enrollment to order and certify covered items and services, the ADA suggested that CMS modify the existing form 855I to include those 10 categories. CMS declined to do so at the time stating it would be too complicated and time consuming to go through the process of changing the form. When CMS subsequently introduced the form 855O for the ordering and referring provider, the ADA once again suggested including the nine recognized specialties and General Dentistry but that suggestion was not adopted. CMS's failure to adopt these categories early on in the rulemaking process has led to significant frustration on the part of dentists trying to comply as well as confusion and misinformation on the part of Medicare Contractors and CMS itself.

While creation of the form 855O was a step in the right direction to simplify the enrollment process, the ADA has suggested CMS could expedite compliance in a manner consistent with the intent of the Affordable Care Act through the use of the information already in hand through the NPI and the NPDB. There is no need to require dentists to go through the enrollment process to ensure CMS has the information necessary to address fraud and abuse concerns. Alternatively, if dentists are required to enroll, CMS must correct the categories to allow that to happen. Dentists cannot be held to compliance if they cannot easily and effectively enroll.

In addition, the ADA contends that CMS already has access to the information needed to maintain program integrity through dentists' National Practitioner Identification (NPI) number and adverse event reporting maintained through the National Practitioner Data Bank (NPDB).

There has been a great deal of confusion and numerous delays around the effective dates of previous requirements for referring practitioners to enroll or opt out. Dentists bear a disproportionate burden of this uncertainty, because they have little incentive to enroll or opt out other than in connection with program integrity initiatives.

Moreover, dentists who merely order and prescribe, but who do not submit claims to Medicare, may be further burdened if they will be required, as a condition of enrollment, to establish a compliance program pursuant to Section 6401(a)(3) of the Patient Protection and Affordable Care Act (PPACA). Because of the relatively small potential for Medicare fraud from dental claims and the potential burden on dentists who are not currently enrolled, the ADA recommends that dentists be excluded from the requirements of this proposed rule.

Disclosing Affiliations. The proposed rule would require providers and suppliers to disclose certain direct and indirect affiliations, which CMS believes could reveal inter-provider schemes involving inappropriate behavior and lead to the denial or revocation of enrollment. ADA believes this is misguided and will not lead to the desired outcome. An individual who is involved in inappropriate behavior would appear to be as likely to omit problematic affiliations from the enrollment form as he or she would be to submit false or fraudulent claims to a federal health care program. The likely effect of this proposal is to burden honest providers with onerous paperwork, without any foreseeable benefit to federal health program integrity.

The proposed rule will require virtually all dentists to obtain an NPI in order to enroll in or opt out of Medicare, which could increase the risk that a dentist's NPI will be used by criminals to submit false claims. The ADA supports CMS's goal of eliminating such abusive practices, and urges CMS to implement procedures to protect practitioners from any unreasonable compliance burden that may also result in NPI misuse by criminals.

The proposed rule contains recordkeeping requirements, and ADA is concerned that certain dentists may not be able to comply because they do not have control over the relevant documents. These may include locum tenens dentists and those who were formerly employed by a government agency or group dental practice. ADA urges CMS to place the burden for any recordkeeping compliance solely on the individual or entity who controls such records.

COST. CMS did not quantify the estimated benefit of the proposed rule, although CMS stated that CMS believes there would be benefits, although unquantifiable, because problematic providers would be kept out of, or removed from, Medicare, Medicaid and CHIP. However, CMS estimates that the annual cost to providers in each the first three years of the proposed rule would be \$289.8 million. ADA believes that the proposed cost is a significant underestimate and that the true cost would not be justified by the value of any benefit that could be achieved by the proposed rule.

CMS estimates that it will take each doctor an average of ten hours to obtain and furnish the information necessary to enroll. ADA believes this is an underestimate. With a five-year look back period that applies to the existence of a direct or indirect affiliation but no look back period for an event triggering disclosure, today's dentists, who are increasingly mobile and who work in increasingly complex practice environments, will likely need more than ten hours to research and gather the necessary information.

Moreover, CMS expects that administrative staff will do so on behalf of doctors. Many small practices may lack administrative staff with the skills to properly accomplish this task, and even highly skilled staff may not have access to specific information about a doctor's past and present affiliations and whether such affiliations have experienced an event triggering

disclosure. Doctors who participate in Medicaid and CHIP will have further forms to fill out, which may vary from state to state. Gathering such information will be challenging for the doctors themselves. In addition, the consequences of making a mistake on the form could be severe, which would also lead many doctors to spend the ten or more hours to undertake this task themselves – hours that would better be spent on patient care. CMS correctly assumes that doctors themselves will complete the shorter 855o forms, but dramatically underestimates the time necessary to complete the form as 0.5 hours. In addition, CMS may have underestimated the value of the doctors' time at \$93.74 (with benefits, \$187.48). The time of many doctors is worth far more, and CMS has not factored in the cost to patients and society of diverting so many hours of doctors' time away from patient care for the completion of government forms.

Since new doctors and providers join the workforce each year, and since previously enrolled doctors have ongoing requirements to report and revalidate enrollment, the expectation that the cost would be limited to the first three years after the effective date of the proposed rule is also unrealistic. The burden of reporting items such as changes of name or business entity will fall especially hard on dentists, who are less likely than other doctors to bill Medicare, and yet would be required to remember to report incidental changes such as new business names and locations or even a change of zip code within the regulatory timeframe or else face potential enforcement action such as revocation of enrollment.

Sincerely,

Carol Gomez Summerhays, D.D.S.
President

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