

November 9, 2010

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-6010-IFC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: RIN 0938-AQ20 – 42 CFR Parts 405, 424, 438, et al. Medicare, Medicaid, and Children’s Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers; Proposed Rule – Federal Register Vol. 75, No. 184, Thursday, September 23, 2010, pages 58204 – 58248.

The American Dental Association (ADA), the world’s oldest and largest dental professional organization representing over 157,000 members in the United States, submits the following comments.

§ 504.370 - § 504.372 “Definitions,” “Suspension, offset, and recoupment of Medicare payments to providers and suppliers of services,” and “Proceeding for suspension of payment”

The ADA supports the proposal to permit CMS to suspend payments to a provider when there is pending an investigation of a credible allegation of fraud, unless the agency has good cause not to suspend payment or to suspend payment only in part. However, under the proposed rule virtually anyone can use a hotline to submit an allegation of fraud concerning an enrolled provider. If the allegation is credible, CMS can suspend payment until a determination is made of insufficient evidence of fraud, or until legal proceedings are completed. The ADA is concerned that an individual such as a disgruntled former employee or a competitor could submit a false allegation of fraud that could cause financial hardship to an honest practitioner. The ADA urges CMS to provide protection for solo and group practice providers under such circumstances, such as a requirement that hotline information not be submitted anonymously or that investigation of an individual provider or group practice be expedited so as not to cause undue financial hardship in the event a credible allegation prove untrue. The ADA also urges CMS to clarify whether payments to a provider could be suspended as a result of an allegation of fraud against an ordering or referring provider.

§ 424.502 “Definitions” and § 424.514 “Application fee” (Medicare, Medicaid, and CHIP)

The ADA supports CMS’s statement in the preamble that applications will not be denied over inconsequential errors or omissions or over errors or omissions corrected in a timely manner. The ADA requests CMS clarify whether the application fee will be refunded in the event that CMS denies an enrollment application received from a provider or supplier covered by an existing moratorium. The ADA urges CMS to provide notice of any applicable moratorium to enrolling providers and suppliers submitting an enrollment application and fee, and to refund any fee paid in connection with an application denied due to a moratorium.

§424.518 “Screening categories for Medicare providers and suppliers”

§ 424.518(a) “Limited categorical risk”

The ADA supports the determination that physician or non-physician practitioners and medical groups or clinics be designated “limited categorical risk.” With respect to the limited categorical risk screening requirements, the ADA believes the language in proposed § 424.518(2) (i) may be overly broad. This language requires the Medicare contractor to “[verify] that a [limited categorical risk] provider or supplier meets **any applicable Federal regulations or State requirements for the provider or supplier type** prior to making an enrollment determination” (emphasis added). We believe the intent is that the contractor verify only that the provider or supplier meet applicable regulations or requirements that qualify the provider or supplier for the appropriate provider or supplier type. However, as written, the language of §424.518(2) (i) could be construed to require the Medicare contractor to verify the provider or supplier’s compliance with virtually every Federal regulation and State requirement that applies to the provider or supplier type. The latter interpretation could subject limited categorical risk providers and suppliers to an overly broad, burdensome, and time-consuming verification process.

§ 424.519(c) (3) “Adjustment in the categorical risk”

The ADA supports CMS in its effort to protect practitioners from fraudulent use of their identities within the Medicare program by providing that CMS may adjust the categorical risk level if a practitioner notifies CMS or its Medicare contractor that another individual is using his or her identity within the Medicare program, and by requiring fingerprinting of high-risk provider and supplier types (but not of individual practitioners who have been the victim of identity or provider number theft). The ADA urges CMS to protect the provider identities of providers and suppliers who enroll in order to submit claims as well as ordering/referring providers and suppliers.

In response to CMS’s request for comments on whether providers and suppliers should be subject to higher levels of screening when the provider specialty does not match clinic type on an enrollment application, the ADA urges CMS to refine the provider enrollment specialty categories to accurately reflect the existing varieties of practitioners, and in particular the categories for dentistry and the dental specialties, in order to reduce the likelihood that practitioners such as dentists will be inappropriately categorized and subject to unwarranted higher levels of screening.

§ 424.530 “Denial of enrollment in the Medicare program” and § 424.570 “Moratoria on newly enrolling Medicare providers and suppliers”

The ADA supports the proposal to permit CMS to impose a temporary moratorium on enrollment of new providers or provider types in a geographic location to prevent fraud and abuse. However, the ADA urges CMS to ensure that such moratoria not prevent health care providers in the geographic location from enrolling as ordering/referring providers when a moratorium may impair such practitioners’ ability to provide patients who are Medicare beneficiaries with needed care. The ADA supports CMS’s statements in the preamble that a moratorium shall not apply to a change of practice locations or to changes of ownership of existing providers or suppliers, mergers, or consolidations.

§ 424.535 “Revocation of enrollment billing and billing privileges in the Medicare program”

We believe that proposed § 424.535(a)(11), which provides that CMS may revoke a currently enrolled provider or supplier’s Medicare billing privileges if a State Medicaid Agency revokes or terminates the provider or supplier’s Medicaid billing privileges, contains an editorial error that makes the language of the proposed rule difficult to understand.

§ 455.23 “Suspension of payments in cases of fraud”

The ADA supports the proposal to permit State Medicaid agencies to suspend Medicaid payments to a provider when there is pending an investigation of a credible allegation of fraud, unless the agency has good cause not to suspend payment or to suspend payment only in part. However, as stated above under § 405.370 - § 455.372, the ADA is concerned about the potential financial harm to a provider who is exonerated after a lengthy suspension based on an allegation of fraud that, while apparently credible when made, is untrue. Proposed § 455.23(c) provides that the suspension will continue until either “(i) the agency or the prosecuting authorities determine that there is insufficient evidence of fraud by the provider,” or “(ii) legal proceedings related to the provider’s alleged fraud are completed.” § 455.23(e) and (f) defines circumstances that would qualify as good cause not to suspend payments or to suspend payment only in part. None of these circumstances would grant relief to an honest provider for whom such a suspension would be financially devastating. The ADA urges CMS to consider a mechanism to expedite investigation and resolution of an allegation in cases where a suspension would cause undue economic hardship to a provider.

§ 455.104 “Disclosure by Medicaid providers and fiscal agents: Information on ownership and control”

We find confusing the use of the term “providers” in proposed § 455.104(c) (1). Proposed § 455.104(a) states that “disclosing entities, fiscal agents, and managed care entities” must provide disclosures. Current § 455.101¹ defines “disclosing entity” to exclude individual practitioners and groups of practitioners, and this definition is not amended in proposed rule § 455.101. We believe that CMS intends § 455.104(c) to apply to providers (as opposed to fiscal agents) who meet the § 455.101 definition of “disclosing entity.” Therefore, we urge CMS to change “providers” in § 455.104(c) to “disclosing entities who are providers.”

Proposed § 455.104(b) requires the State Medicaid agency to collect certain sensitive personal information (name, address, date of birth, and Social Security number), the inappropriate use or disclosure of which could result in financial harm to individuals. The ADA urges CMS to require State Medicaid agencies to effectively protect such information by developing and implementing specified effective data security policies and procedures, and to notify individuals in the event of a breach.

§ 455.410 “Enrollment and screening of providers”

Proposed § 455.410(b) states: “The State Medicaid agency must require all ordering or referring physicians or other professionals providing services under the State plan or under a waiver of the plan to be enrolled as participating providers.” This language appears to mean that a practitioner who does not provide services under either the State plan or under a waiver of the plan is not required to enroll in order to order or refer. The ADA supports this interpretation, and urges CMS to confirm whether this interpretation is correct, or, if not correct, to clarify which practitioners are required to enroll as ordering or referring practitioners.

§ 455.414 “Reenrollment”

The ADA urges CMS to clarify (1) whether § 455.414 requires providers to re-enroll every 5 years (or merely requires State Medicaid agencies to screen all providers every 5 years), (2) whether the

¹ “Disclosing entity means a Medicaid provider (other than an individual practitioner or group of practitioners), or a fiscal agent.” 42 CFR 455.101.

reenrollment and/or screening will apply to all enrolled providers, including ordering or referring physicians or other professionals, and (3) whether CMS will give notice every 5 years of the need to re-enroll to each enrolled provider (failure to notify enrolled providers of the need to re-enroll could result in termination of enrollment, as failure to submit timely information can result in termination or denial of enrollment under proposed § 455.416(a) and (d)).

§ 455.418 “Deactivation of provider enrollment”

Proposed § 455.418 requires State Medicaid agencies to deactivate the enrollment of providers who have not submitted claims or made referrals that resulted in Medicaid claims for a period of 12 months. If proposed § 455.410 “Enrollment and screening of providers” requires practitioners who do not provide services under the State plan or under a waiver of the plan to enroll as ordering and referring providers in order to refer patients who are Medicaid beneficiaries for covered services or to order covered items for patients who are Medicaid beneficiaries (see comment above under § 455.410), then deactivating the enrollment of such ordering and referring practitioners after a period of 12 months’ inactivity would be a hardship on such ordering and referring practitioners. Such practitioners, whose practices may include few Medicaid beneficiaries, would be required to reactivate their enrollment and undergo re-screening annually, whereas, under proposed § 455.414 most other providers are required to re-enroll and undergo re-screening every 5 years. The ADA urges CMS to clarify the enrollment and re-enrollment responsibilities of ordering and referring practitioners who do not provide services under the State plan or under a waiver of the plan.

§ 455.450 “Screening categories for Medicaid providers”

Proposed § 455.450(a)(1) requires State Medicaid agencies to verify that a provider designated as a “limited” categorical risk “meets any applicable Federal regulations, or State requirements for the provider type prior to making an enrollment determination.” The ADA repeats the concerns stated above under § 424.518 with respect to the limited categorical risk screening requirements for Medicare providers. The ADA believes the standard in proposed § 455.450(a) (1) may be overbroad. We believe the intent is that the State Medicaid agency verifies only that the provider or supplier meets applicable regulations or requirements that qualify the provider or supplier for the appropriate provider or supplier type. However, as written, the language of §455.450(a) (1) could be construed to require the State Medicaid agency to verify compliance with every Federal regulation and State requirement applicable to the provider or supplier type. The latter interpretation could subject “limited categorical risk” providers and suppliers to an overly broad, burdensome, and time-consuming verification process.

§ 455.460 “Application fee”

Proposed section § 455.460 (a) (1) permits States to collect application fees from prospective or re-enrolling provider other than “individual physicians and non physician practitioners.” Given that every Medicaid provider has his or her own billing number and the definition of provider used in this rule, it is our understanding that application fees would not be applicable to individual physicians and non-physician practitioners, regardless of the type of practice setting. However, the ADA requests clarification from CMS to ensure this interpretation is accurate and that regardless of whether a physician or non-physician practitioner was organized in a partnership or other type of entity, the application fee would not be applicable. The ADA also urges CMS to clarify that the exemption under § 455.460 (a) (2) (i) (A) applies to practitioners, group practices, and clinics enrolled as ordering and referring providers under Title XVII of the Act.

§ 455.470 “Temporary moratoria”

The ADA repeats its comment under § 424.530 above in support of the proposal to permit CMS to impose a temporary moratorium on enrollment of new providers or provider types in a geographic location to prevent fraud and abuse. However, the ADA also repeats its comments under § 424.530 above, and in addition, the ADA urges CMS to ensure that a moratorium imposed by either the Secretary or the State Medicaid agency not prevent health care providers from enrolling as ordering/referring providers when to do so may impair such practitioners’ ability to provide their patients who are Medicare or Medicaid beneficiaries with needed care.

§ 457.990 “Provider and supplier screening, oversight and reporting requirement” (CHIP and Medicaid)

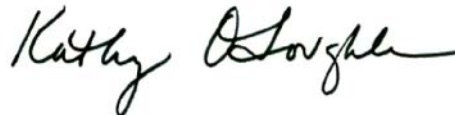
CMS proposes in new regulation § 527.990 that all of the provider screening, provider application, and moratorium regulations that apply to Medicaid providers will apply to providers that participate in CHIP, and that State Medicaid agencies are responsible for screening Medicaid-only providers. The ADA restates its comments above regarding Medicare provider screening, provider application, and moratorium regulations here, with respect to CHIP and Medicaid.

If you or your staff has any questions, please contact Dr. Frank Kyle in our Washington, DC Government Affairs office at 202-789-5175 or kylef@ada.org.

Sincerely,



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President



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