PUBLICATION

Proposed Enrollment Rule Changes - de Facto Exclusion? [Ober|Kaler]

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Proposed rules, touted as enhancing the provider enrollment process, would provide CMS with sanction authority that closely parallels the OIG's exclusion authority. Under the proposed rules, CMS would have expanded bases to deny a new enrollment and significantly expanded authority to revoke billing privileges.

The increased sanction authority is not, however, accompanied by any associated changes to ensure due process protections and a timely appeals process for providers or suppliers, protections needed when the denied or revoked enrollment is overturned on appeal. Furthermore, there are no changes protecting providers and suppliers from collateral consequences during the appeals process or to ensure that billing privileges are promptly conveyed or restored following a successful appeal. This article highlights key changes proposed by CMS and proposed changes to which CMS specifically requested comments in its March 1, 2016, "Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process; Proposed Rule [PDF]." Comments must be received by **April 25, 2016**.

CMS focused on several changes designed to ensure that enrolled providers and suppliers would no longer be able to "circumvent Medicare requirements through name and identity changes as well as through elaborate, inter-provider relationships." CMS acknowledged its current revocation rules, which revoke the billing number (i.e., the National Provider Identifier or NPI number) and terminate the participation agreement of the enrolled provider or supplier, do not require the revocation of other company enrollments with different NPI numbers, or even different tax identification numbers, or prevent the owners from using a new NPI number to operate the same business serving the same beneficiaries. CMS also expressed concern that its current rules do not go far enough to prevent those in ownership or control from forming a new entity to perform the same or similar services after terminating an enrollment to avoid paying a Medicare debt. Under the proposed rules, CMS's expanded denial and revocation bases could directly affect other Medicare and Medicaid enrollments under common ownership or control.

- All Practice Locations Included in Revocation: The proposed regulations would allow CMS to revoke billing privileges of all practice locations, irrespective of whether the locations are included as part of the same enrollment or are locations that have been reported under a different enrollment under common ownership or control. This would affect companies that utilize subsidiaries or affiliates for business reasons, such as to limit liability or keep revenue streams separate. For example, all nursing facilities with common ownership or control, each enrolled under a different legal entity name, tax identification number, and each assigned its own CMS Certification Number, could be revoked based on noncompliance at one of the separately enrolled practice locations. To determine the number of locations to be revoked, CMS identified a number of factors to be considered, including: the noncompliance reasons that led to the revocation and how long the noncompliance had occurred, the number of additional locations, any prior history of final adverse actions, the amount billed to Medicare at the noncompliant location, and the degree of risk to the Medicare trust funds.
- Revocations Related to Outstanding Debts, Payment Suspensions, and Adverse Actions of Affiliated Providers and Suppliers: CMS expressed great concern over providers and suppliers that "disguise true ownership by the use of nominee owners" and noted the use of complex organizational

structures that may pose an undue risk to Medicare. CMS proposed the following rules, and procedures to apply the new rules, to address these concerns:

- Adding a definition for *affiliation* to include (i) an individual or entity with a 5 percent or more direct or indirect ownership, (ii) general or limited partnership interest irrespective of the percentage ownership, (iii) interests in which an individual or entity exercises operational or managerial control irrespective of whether by contract or other arrangements, (iv) an officer or director of a corporation, and (v) a reassignment relationship. *CMS is requesting comments on whether the inclusion of a reassignment relationship is likely to "lead to additional information that may prevent fraud, waste and abuse."*
- Requiring owners and controlling organizations and individuals to disclose on an initial enrollment or revalidation application if the organization or individual currently has or had within the prior five years, an "affiliation" with a currently or formerly enrolled Medicare, Medicaid or CHIP provider or supplier with: (i) an uncollected debt that had been referred to the U.S. Treasury Department, (ii) a payment suspension, (iii) an exclusion, or (iv) a denied or revoked enrollment irrespective of the reason, which would include situations in which an enrollment was voluntarily terminated to avoid a revocation. Bear in mind that although the look-back period is five years, it is irrelevant when the actual adverse action occurred or was imposed. Therefore, this new regulation would require any entity or individual falling under the definition of *affiliation*, noted above, to track the status of each Medicare- and Medicaid-enrolled provider or supplier in which it currently has or has had an affiliation in the past five years to know if there are any reportable events to disclose. CMS is proposing the application of a *reasonableness* standard when making determinations whether the affiliate knew or should have known about the outstanding debt or adverse action. *CMS is requesting comments on whether this required disclosure should include additional ownership or managerial interests or other relationships, whether five years is an appropriate look-back period, whether there should be an established "reasonableness test," and whether the "disclosure should be restricted to certain denial, revocation and termination reasons and, if so, what those reasons should be."*
- CMS would then apply certain factors (e.g., factors related to the degree and length of the affiliation, the amount of an unpaid debt and if payments are being made, and the reason for the adverse action) to determine if any disclosed affiliation "poses an undue risk of fraud, waste or abuse." *CMS is soliciting comments on whether there are additional factors to be considered, if any of the proposed factors should not be considered, and if any factors should be given more or less weight.*
- CMS confirmed it would apply its proposed regulations irrespective of whether the provider or supplier had reported the affiliation relationships on its CMS 855 enrollment application form.
- Therefore, both the failure to fully disclose the requested information and a finding that the affiliation poses an undue risk would be a basis for CMS to deny the initial enrollment application or revoke the enrollment of the revalidating provider or supplier.
- Under the proposed rules, the affiliation disclosure would only be required at the time of an initial enrollment or during a revalidation. Even so, CMS would have the authority to revoke an existing provider or supplier upon determining that an affiliation poses an undue risk, even when the affiliation is identified between revalidation cycles such that the provider or supplier was not yet required to disclose it.

In addition to these proposed rules for affiliation relationships, CMS proposes to expand its revocation authority to any provider or supplier with an unpaid debt that is reported to the U.S. Department of Treasury.

- Enrollment Denial – Similar Enrollment: CMS proposes to deny an enrollment if the provider or supplier has had a Medicare revocation under a different name, NPI number or business identity. To make its determination to deny an application, CMS would consider various factors, including the

degree of commonality of ownership and control, geographic locations, enrollment type, business structure, and any evidence of the similarity of the enrollee and the revoked provider or supplier. CMS cautioned not to assume "that having different owners, locations or business structures would automatically result in a finding that the two are not the same."

In addition to the proposed rules that focus on organizational structures and affiliations, the proposed rulemaking includes rules that would apply to individuals with denied or revoked enrollments. Some of these proposed rules include:

- Ordering and Referring Rules Expanded: Under the current rules, certain Medicare covered items and services must be ordered by a physician or nonphysician practitioner (NPP) who has an active enrollment record in PECOS or has validly opted out of Medicare. Under this rule, the provider or supplier must confirm the Medicare enrollment or opt-out status of the physician or NPP prior to submitting a claim to avoid denied claims. Furthermore, under CMS's current revocation authority, if a physician or NPP denies ordering these Medicare-covered items and services, it is the provider or supplier that faces a potential revocation. Under the proposed rules, CMS would have the authority to revoke the physician's or NPP's enrollment when CMS finds an abusive pattern or practice of ordering. Additionally, CMS is expanding the ordering and referring rules to "ordering, certifying, referring or prescribing Medicare Part A or B services, items or drugs." CMS identified factors it would consider in making a revocation decision, stating it would focus on "egregious patterns" that fall outside of acceptable practice standards. As a related change, CMS determined it would prevent an opt-out physician or NPP who has a revocation from being able to order, prescribe or certify the need for a Medicare-covered item or service.
- Failure to Report Enrollment Updates: Currently, CMS has authority to revoke the billing privileges of an individual or group of physicians or NPPs that fails to report a change in practice location or adverse actions. CMS proposes to extend this revocation basis to the failure to timely report any change in enrollment data. Moreover, the proposed rules would extend the timely reporting requirements to all other types of providers and suppliers. Under its existing rules, CMS has revocation authority for noncompliance with its "enrollment requirements"; however, in revocation cases CMS has had to prove that a requirement is an enrollment requirement. This expanded authority would provide a specific basis to revoke if a provider or supplier delays in reporting or fails to report a change in its enrollment data.

In addition to the changes related to reasons to revoke or deny an enrollment, CMS proposes the following new or changed rules related to the length of the sanction:

- Increase in the Reenrollment Bar: CMS proposes to increase the length of the reenrollment bar, which is currently a one- to three-year bar, to up to 10 years for an initial revocation and up to 20 years if the provider or supplier is being revoked for the second time. Furthermore, CMS proposes to add up to three more years to the reenrollment bar for a provider or supplier found to be attempting to circumvent the bar by reenrolling under a different name, numerical identifier or business identity.
- Initiation of a Reapplication Bar: Currently, if an enrollment application is denied, the provider or supplier may submit a new enrollment application if the denial is not appealed and the appeal filing deadline has passed. Under its proposed rule, CMS could establish an up to three-year bar to reapplication if an enrollment application is denied because the provider or supplier submitted false or misleading information or omitted information in order to gain enrollment.

Ober|Kaler's Comments

The proposed rules could be justified if denied enrollments and billing privilege revocations were limited to providers and suppliers that were committing acts that resulted in fraud, waste or abuse to the Medicare trust fund or harm to Medicare beneficiaries. Unfortunately, that is not always the case, especially since the existing rules allow for revocations due to inadvertent errors, even in situations in which there have been no Medicare payment or service provided to any Medicare beneficiary. For example, a provider or supplier could be revoked for inadvertent billing errors resulting in a less than one percent (1%) error rate; for billing errors even when the claims were not paid as a result of the error; for the failure to obtain a few required certifications of the medical necessity for services; and for the failure to report a change in a practice location when a location was closed, even if no claims were submitted from the closed location.

As noted above, the proposed expanded sanction authority comes with no accompanying protections. Currently, the appeals process, which is a two-step process, provides an extremely short time frame for a provider or supplier to submit evidence demonstrating its level of compliance with the rules. Within that process, the provider or supplier may be denied access to the documentation supporting the enrollment denial or revocation, such as the site verification visit report or the information identified during a Medicare or Medicaid contractor investigation, further limiting the ability to mount a defense. When a provider or supplier is retroactively revoked, the revocation is most often accompanied by overpayment demands for the services billed from the effective date of the revocation. The unpaid overpayment demands are often reported to a recovery contractor or even the U.S. Treasury Department, resulting in expenses not only to appeal the revocation but expenses to appeal the overpayment demands and dispute the debt referral. There is no right to an expedited appeal, so the lack of Medicare payments while awaiting an appeal date has resulted in providers and suppliers simply having to close or sell the business, even in situations when the appeal may have had a successful outcome. And, when the appeal is successful, there is no process to ensure that billing privileges are timely restored, that the enrollment record is updated to remove the notation that the provider or supplier had a revocation, that any associated overpayment demand is reversed, or that referred debts are recalled.