CMS proposes increased requirements to the provider enrollment process

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On March 1, 2016, the Centers for Medicare & Medicaid Services (CMS) published a proposed rule addressing program integrity enhancements to the provider enrollment process (the Proposed Rule). The Proposed Rule, among other provisions, implements portions of the Affordable Care Act that require Medicare, Medicaid and Children's Health Insurance Program (CHIP) providers and suppliers to disclose certain current or previous affiliations with a provider or supplier and permit CMS to deny enrollment based on affiliations determined to pose a risk of fraud and abuse. The Proposed Rule aims to address certain program integrity issues and vulnerabilities by making sure that individuals who pose a risk to the Medicare program are removed or kept out of the program and allowing CMS to take action against unqualified and fraudulent entities. CMS is accepting comments on the Proposed Rule through April 25, 2016.

Background

Because of lingering concerns that providers and suppliers could too easily evade then-existing federal health care program integrity provisions, the Affordable Care Act increased the disclosure requirements for entities enrolling or revalidating with Medicare, Medicaid or CHIP. The Proposed Rule aims to implement these restrictions and provide broader powers to CMS to deny, revoke or bar reenrollment of providers and suppliers.

Disclosure of affiliations

Currently, the Medicare program enrollment form, Form CMS-855, does not collect data about a provider or supplier's prior affiliations. CMS believes that having knowledge of prior affiliations will assist its program integrity efforts by revealing potential inter-provider schemes involving inappropriate behavior. CMS and the Office of Inspector General (OIG) have had longstanding concerns about individuals and entities that enroll in Medicare, or otherwise own or operate enrolled providers or suppliers, which accumulate large debts or engage in other inappropriate activities and then depart the Medicare program, only to reenter the program using a different name or business identity or shift their business to another commonly owned enrolled entity. CMS does not currently have authority to prevent this behavior unless the owner or managing individuals or organizations are convicted of a felony, excluded from the Medicare program or debarred. In many cases, owners and managers of fraudulent entities hide behind the organizational structure itself when they are, in fact, one operation. To address this concern, the Proposed Rule would allow CMS to take immediate action against these persons and entities.

Specifically, the Proposed Rule would require providers and suppliers to disclose on the Form CMS-855 affiliations with individuals or entities that:

- Currently have an uncollected debt to Medicare, Medicaid or CHIP, regardless of (i) the amount of the debt; (ii) whether the debt is currently being repaid; or (iii) whether the debt is currently being appealed.
- Have been or are subject to a payment suspension under a federal health care program, regardless of when that payment suspension occurred or was imposed.
- Have been or are excluded from participation in Medicare, Medicaid or CHIP, even if the exclusion is under appeal.

- Have had their Medicare, Medicaid or CHIP enrollment denied, revoked or terminated, regardless of (i) the reason for the denial, revocation or termination; (ii) whether the denial, revocation or termination is currently being appealed; or (iii) when the denial, revocation or termination occurred or was imposed.

The Proposed Rule defines an "affiliation" as:

- A five percent or greater direct or indirect ownership interest of an individual or entity in another organization;
- A general or limited partnership interest (regardless of the percentage) that an individual or entity has in another organization;
- An interest in which an individual or entity exercises operational or managerial control over or directly or indirectly conducts the day-to-day operations of another organization, either under contract or through some other arrangement, regardless of whether or not the managing individual or entity is a W-2 employee of the organization;
- An interest in which an individual is acting as an officer or director of a corporation; or
- Any reassignment relationship under 42 CFR Section 424.80.

The provider or supplier must disclose detailed information about each reported affiliation, including: (i) identifying information, including legal name and "doing business as" name, TIN and NPI; (ii) the reason for disclosing the affiliated provider or supplier; and (iii) specific data regarding the affiliation relationship, including length of relationship, type of relationship and degree of affiliation.

The Proposed Rule states "that the affiliated provider or supplier need not have been enrolled in Medicare, Medicaid or CHIP when the disclosing party had its relationship with the affiliated provider or supplier." The disclosable event could occur before the affiliation in question or after it ended — the duty to report would be unchanged under the Proposed Rule.

Providers and suppliers would also have to report new or changed information regarding existing affiliations or any new affiliations. However, changed information regarding prior affiliations would not have to be reported, except as part of a revalidation.

CMS would use all of this additional collected information to determine whether an "undue risk of fraud, waste or abuse" was suggested. Such a finding would result in either denial or revocation, as applicable, of a provider or supplier's Medicare enrollment. No actual fraud, waste or abuse would need to be found to impose denial or revocation, only an undue risk of it. While the Proposed Rule does not define specifically what "undue risk" is, CMS states that the factors to be considered in evaluating its presence would include:

- The duration of the affiliation;
- Whether the affiliation still exists, or how long since it did exist;
- The degree and extent of the affiliation (e.g., percentage of ownership);
- The reason for termination of the affiliation;
- What the disclosable event was;
- When the event occurred;
- Whether the affiliation pre-dated the event's occurrence;
- The characteristics of the uncollected debt, if applicable; and
- Other factors or evidence CMS may deem relevant.

Increased CMS authority

The Proposed Rule would give CMS increased authority to deny or revoke a provider or supplier's enrollment if they failed to fully and completely disclose the required information when the provider "knew or should reasonably have known" the information may result in (i) denial of the provider or supplier's application or (ii) revocation of the provider or supplier's Medicare enrollment. CMS also proposes making three changes to its reenrollment imposition: 1) increasing the maximum reenrollment bar period from three to 10 years; 2) creating the ability to add an additional three-year bar onto any existing reenrollment bar if

CMS determines that the provider or supplier was actively trying to circumvent its existing enrollment bar; and 3) creating an enrollment bar for up to 20 years for providers or suppliers who are being revoked for the second time. All of the bars would apply to current, former and future business names, identifiers or business identities.

Other situations in which the Proposed Rule expands CMS' ability to either revoke or deny enrollment are:

- The provider or supplier has already been denied or revoked under a different business identifier. CMS proposes to assess the similarity of the two entities by comparing location, identity of managing and controlling employees, business structure, type of services provided, and any other evidence of similarity or attempts to circumvent any reenrollment or revocation bars.
- If the provider or supplier billed for services utilizing a location it knew or should have known did not comply with the applicable Medicare enrollment requirements. The revocation or denial could, depending on the facts, apply to all locations of the provider or supplier, not just the non-compliant location.
- When there is a pattern or practice of a physician or eligible professional ordering or referring services or drugs that is abusive, a threat to Medicare beneficiaries (i.e., medically unnecessary) or otherwise fails to meet Medicare requirements. While CMS will evaluate a variety of factors in making a determination under this section, it stresses that it is most concerned with "egregious patterns of ordering, certifying, referring or prescribing that fall well outside standard, acceptable practices."
- If a prospective provider or supplier was denied enrollment because it submitted false or misleading information or omitted information on its enrollment application, CMS could impose a three-year reapplication bar to that provider or supplier.
- When a provider or supplier has an existing debt that CMS refers for collection to the Department of Treasury, CMS may revoke the provider or supplier's enrollment.
- The failure of a provider or supplier to timely report any change in Medicare enrollment could now be grounds for revocation. Previously, only failures to report the addition of new practice locations or change to a final adverse action were grounds for revocation. Now any failure to timely report a required change (including zip code or phone number changes, medical records storage facilities, change in officers, etc.) could be grounds for revocation. While CMS states that it would not intend to target innocent reporting failures, the Proposed Rule would create the ability to do so.
- CMS would expand its ability to revoke an enrollment for prior payment suspension to include managing organizations, individuals and all types of providers and suppliers. Under current law, this type of revocation only applies to current owners, physicians and non-physician practitioners. The Proposed Rule would also allow similar Medicare revocation as a result of any state Medicaid payment suspension.
- If a state Medicaid program terminated or suspended a provider or supplier from participation in the state program or a state license was revoked or suspended, even in a different state from where the provider or supplier was enrolling, CMS could deny or revoke the provider or supplier's Medicare enrollment. Such denial or revocation could extend to all enrollments held by the provider or supplier.
- The voluntary termination of a Medicare enrollment in order to avoid a potential revocation and its resulting reenrollment bar would now be grounds for a revocation, effective the day before the voluntary termination request is received.

Other changes contained in the Proposed Rule

The Proposed Rule also includes the following additional changes to the Medicare enrollment requirements:

- A physician or eligible professional would need to be enrolled in Medicare or have validly opted out of Medicare in order to order, certify, refer or prescribe any Part A or Part B service, item or drug. Documentation for such orders, certifications, prescriptions or referrals would now have to be maintained for seven years.
- Existing providers and suppliers would not be able to relocate an existing practice site into an enrollment moratorium area.

- CMS may reject a DMEPOS supplier's new or continued use of a surety bond issuer if the issuer has failed to submit payment to CMS under any surety bond it has issued.
- The reactivation requirements and process by which a provider or supplier could reactivate its privileges would be clarified to allow reactivation after deactivation for any reason and to allow CMS, at its discretion, to request a complete 855 application to affect the reactivation.

Conclusion

The Proposed Rule contemplates some sweeping changes to many facets of the regulations governing Medicare enrollment. While CMS has stated that its goal is to target egregious behavior and violations of the Medicare enrollment rules, the Proposed Rules will place new and dramatic burdens on all existing and potential providers and suppliers. These requirements implicate both the operations of the provider or supplier itself as well as the operations and enrollment history of past affiliates. This will require a great deal of due diligence and effort on the part of providers and suppliers. Because CMS is accepting comments on the Proposed Rule until April 25, 2016, providers and suppliers should consider sending comments to CMS, particularly on the administrative and operational burdens the Proposed Rules could impose.

For questions regarding the Proposed Rule, its specific implications to you or your facility, or to discuss the filing of a comment with CMS, please contact a member of Bricker & Eckler's Health Care group.

Authors