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Trap for the Wary Becomes a Minefield; Beware the New Provider Enrollment Rule

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"You are the company you keep." On September 5, 2019, the Centers for Medicare & Medicaid Services (CMS) released a final rule that takes this adage to heart. Promulgated pursuant to the Affordable Care Act,[1] the Final Rule authorizes CMS to deny or revoke Medicare/Medicaid billing privileges for certain "bad acts" of a provider or supplier's current and past affiliates and otherwise significantly expands CMS' enforcement authority in the provider enrollment space. The Final Rule establishes new enrollment disclosure obligations requiring Medicare, Medicaid, and Children's Health Insurance Program (CHIP) providers and suppliers to research and report on the actions of their affiliates.[2] Never has it been more important for providers and suppliers to "choose their friends wisely." This article summarizes the affiliation disclosure requirements and other new enhancements to CMS' provider/supplier screening authority under the Final Rule.

Affiliation Disclosure Requirements

In general, the Final Rule requires providers/suppliers submitting initial enrollment and revalidation applications for Medicare, Medicaid, or CHIP to disclose certain current and previous affiliations with other providers or suppliers that have been subject to any of the following: (1) has uncollected Medicare, Medicaid or CHIP debt; (2) has been or is subject to a payment suspension under a federal health care program; (3) has been excluded by the Office of Inspector General (OIG) from participation in Medicare, Medicaid, or CHIP; or (4) has had its billing privileges denied or revoked. CMS refers to these as "disclosable events." If CMS determines the affiliation poses an undue risk of fraud, waste, or abuse, CMS is authorized to deny or revoke the provider/supplier's billing privileges.

In its March 1, 2016 proposed rule, CMS proposed to require all initial and revalidation enrollment applications to include affiliation disclosures.[3] Serious concerns were raised about the significant burden this proposal placed on providers/suppliers. To the relief of many, CMS took steps to reduce this burden in the Final Rule. As finalized, the new regulations require affiliation disclosures in initial and revalidation enrollment applications only when requested by CMS. CMS will make this request after it determines, through its own research of already-available data, that the provider/supplier has at least one affiliation that includes a "disclosable event." In the Final Rule, CMS also advised that even though the Final Rule becomes effective on November 4, 2019, no affiliation disclosure requests will be made until both the paper CMS 855 forms and online Provider Enrollment, Chain, Ownership System (PECOS) enrollment application have been revised to include an affiliation disclosure section.

Although it appears that most providers/suppliers have been given a temporary reprieve from the new affiliation disclosure obligations, CMS promises to eventually promulgate a "subsequent final rule" that will require all providers and suppliers to disclose affiliation information. Providers/suppliers should take advantage of the time that has been given to them to familiarize themselves with the new affiliation disclosure requirements. Here is what they need to know.

1. Providers/suppliers should map out and examine which relationships constitute an "affiliation" under the Final Rule.

Determining which relationships constitute a potentially reportable "affiliation" will take time for many providers/suppliers. In fact, this process could involve an analysis of a complex web of organizations and individuals. The Final Rule not only requires the provider/supplier to report its "affiliations," but also to review and potentially report the affiliations of the provider/supplier's individual and organizational owners and managing employees. In short, providers/suppliers must review any relationships over the previous five years between currently or formerly enrolled Medicare, Medicaid, or CHIP providers/suppliers and those individuals/organizations required to be listed in Sections 2, 5 and 6 of the provider/supplier's CMS 855 enrollment application.

The Final Rule establishes a broad definition of "affiliation," which will impose a significant burden on providers/supplier to identify and track relationships that constitute potentially reportable affiliations. This is particularly true for larger provider/supplier organizations or health systems. If, over the previous five years, the provider/supplier or one of its owners/managing employees held any of the following interests in a currently or formerly enrolled Medicare, Medicaid, or CHIP provider, it constitutes a potentially reportable "affiliation":

- A 5% or greater direct or indirect ownership interest.
- A general or limited partnership interest (regardless of the percentage).
- 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 currently or formerly enrolled in Medicare, Medicaid, or CHIP. Note that the individual/organization can exercise managerial control through a contractual or other type of arrangement and is not required to be a W-2 employee.
- An interest in which an individual is acting as an officer or director of a corporation currently or formerly enrolled in Medicare, Medicaid, or CHIP.
- Any reassignment relationships.[4]

2. Only affiliations that include a "disclosable event" must be reported.

Once the provider/supplier develops a list of affiliations, it must decide which affiliations require disclosure, if any. Not all affiliations are required to be disclosed through the enrollment process. Only affiliations that include one or more of the below "disclosable events" must be reported.

- ***Current uncollected Medicare, Medicaid, or CHIP Debt***—In the Final Rule, CMS explained that "uncollected debt" refers to any debt stemming from a Medicare, Medicaid, or CHIP overpayment for which CMS or the state has sent notice of the debt, such as a demand letter or other formal request for payment, to the affiliated provider or supplier and which has not been fully repaid. Civil monetary penalties and assessments are also included. Any affiliated providers/suppliers with an unpaid debt, regardless of the amount owed or if it is subject to appeal, must be reported.
- ***Payment suspension under a federal health care program***—In the Final Rule, CMS clarified that any affiliated provider/supplier who has been subject to payment suspensions under a federal health care program, regardless of the specific regulatory basis involved must be reported.
- ***Exclusion by the OIG from participation in Medicare, Medicaid or CHIP***—Affiliated provider/supplier exclusions must be reported regardless of whether the exclusion is being appealed or when it occurred or was imposed.

- ***Medicare, Medicaid, or CHIP Enrollment Denial, Revocation, or Termination***—Even voluntary terminations must be disclosed if the affiliated provider/supplier voluntarily terminated "to avoid a potential revocation or termination."[5] Providers/suppliers must report all denials, revocations or terminations of affiliated providers/suppliers, regardless of when the it happened or why it happened.[6]

It is important to note that any "disclosable events" currently under appeal must be reported, but those "disclosable events" overturned on appeal are not reportable. Also, even those "disclosable events" that occurred outside of the period of affiliation must be reported. CMS did not establish a lookback period for disclosable events. This will require providers/suppliers to make reasonable efforts to research whether an affiliate provider/supplier was subject to a disclosable event many years in the past even if the affiliation was just recently established.

3. CMS will determine whether any reported affiliations pose an "undue risk" of fraud, waste or abuse.

No affiliation disclosures will be required until the CMS 855 enrollment forms and PECOS has been updated to allow providers/suppliers to report the information about affiliations with disclosable events.[7] Once the enrollment forms are updated and CMS requests an affiliation disclosure, if a provider/supplier fails to "fully and completely" disclose required affiliation information, CMS has the authority to deny or revoke the provider/supplier's billing privileges.[8] After the provider/supplier discloses the information, CMS will review the affiliation information. If CMS determines that an affiliation poses an undue risk of fraud, waste, or abuse, CMS may deny or revoke the provider/supplier's billing privileges.[9]

Throughout the Final Rule, CMS assures providers/suppliers that it will make "undue risk" determinations with caution. The new regulations explain that CMS will consider the following factors when deciding:

- The duration of the affiliation.
- Whether the affiliation still exists and, if not, how long ago it ended.
- The degree and extent of the affiliation.
- If applicable, the reason for the termination of the affiliation.
- The type of disclosable event.
- When the disclosable event occurred or was imposed.
- Whether the affiliation existed when the disclosable event occurred or was imposed.
- If the disclosable event is an uncollected debt, the amount of the debt, whether the affiliated provider/supplier is repaying the debt, and to whom the debt is owed.
- If a denial, revocation, termination, exclusion, or payment suspension is involved, the reason for the disclosable event.
- Any other evidence that CMS deems relevant to its determination.[10]

4. Affiliation disclosure requirements and Medicaid.

State Medicaid programs are required to adopt the same affiliation disclosure requirements. The Medicaid affiliation disclosure rules will not become effective until the Medicaid programs revise their electronic and paper enrollment forms. State Medicaid programs are permitted to implement the new rules in one of two ways: (1) state Medicaid programs may require all newly enrolling and revalidating Medicaid providers to report affiliations with disclosable events, or (2) state Medicaid programs may require affiliation disclosures only upon request by the state. It will be important for providers/suppliers to pay attention to which option is chosen by the states in which the providers/suppliers do business.

5. More guidance will be issued by CMS regarding affiliation requirements.

Although CMS has established a more targeted approach to implement the new affiliation disclosure requirements, CMS seeks public comment on potential approaches for obtaining affiliation information from all initially enrolling and revalidating providers/suppliers. Comments must be submitted to CMS by November 4, 2019. Once CMS has an opportunity to review the public comments, it will publish a "subsequent final rule" on the process.

CMS also promises to publish subregulatory guidance on the affiliation reporting requirements. CMS acknowledges that it may difficult for providers/suppliers to access "disclosable event" information for all affiliations, and indicates that it will publish subregulatory guidance to explain what the agency considers to be reasonable efforts made by or on behalf of a provider/supplier to research and report affiliations with disclosable events.

CMS' Enhanced Enforcement Authority

1. Enrollment non-compliance can jump from one enrollment to another, and one legal entity to another, exponentially increasing the cost of mistakes.

Under the Final Rule, CMS will have the ability to deny or revoke a provider or supplier's enrollment in the Medicare program if it determined that the provider or supplier is currently revoked under a different name, numerical identifier, or business entity and the reenrollment bar period that attaches to an enrollment revocation has not expired.[11] CMS will determine the "degree of commonality" between the entities or other enrollments to determine whether to deny or revoke a separate enrollment by considering the following factors:

- Owning and managing employees and organization (whether listed on the CMS 855 application or not);
- Geographic location;
- Provider or supplier type;
- Business structure; and
- Any evidence indicating that the two parties are similar or that the provider/supplier was created to circumvent the revocation and reenrollment bar.[12]

Commenters to the Final Rule inquired as to whether CMS would automatically determine that another provider or supplier enrollment has a "degree of commonality" with the denied or revoked provider/supplier was attempting to circumvent enrollment requirements; CMS declined to say no, but did say that an intent to circumvent the enrollment requirements was only one of several factors to be considered.[13]

In addition, CMS may now revoke a provider or supplier's Medicare enrollment(s) if the provider or supplier billed for services performed at or items furnished from a location that it knew or should have known did not comply with Medicare enrollment requirements.[14] In determining whether another location's revocation should be revoked, CMS will consider:

- The reason for and the specific facts behind the location's non-compliance;
- The number of additional locations involved;
- Whether the provider or supplier has a history of final adverse actions or payment suspensions;
- The degree of risk that the location's continuance poses to Medicare;
- The length of time the location was non-compliant;

- The amount billed from the non-compliant location; and
- Other information deemed relevant by CMS.[15]

A frequent reason for a provider or supplier's failed site visit is a relocation that has not been timely reported to CMS, or the population of the site where health care is provided on the Medicare enrollment form with another address for the provider or supplier (such as the correspondence address). Such events could certainly cause a legal organization to lose ALL of its Medicare enrollments. CMS refers to a "false storefront" in the commentary to the Final Rule if the provider or supplier is billing using the old location as the site of service,[16] which suggests that CMS may review this kind of mistake unfavorably under the Final Rule.

These new provisions make clear that the consequences for enrollment mishaps can be devastating to provider/supplier organizations that operate more than a single provider or supplier location.

2. CMS foreshadows more provider/supplier enrollment revocations for failure to timely report any changes to Medicare enrollment information.

CMS enacted an expanded regulation to allow revocation of any provider or supplier's Medicare enrollment for failure to timely report changes to Medicare enrollment information.[17] Currently, only specific provider types (physicians, nonphysicians, and other nonphysician practitioners) have a regulation that specifies failure to timely report enrollment changes as the basis for a revocation, and revocation is enumerated only for certain specific enrollment information.[18] In addition, there is a current regulation that provides that noncompliance with enrollment rules can provide a basis for revocation for all provider and supplier types.[19] CMS indicates that it is not truly expanding its revocation authority, just consolidating the rules in one place.[20]

The Final Rule indicates that in deciding to revoke an enrollment, CMS will consider the following:

- Whether the data was reported;
- If the data was reported, how late;
- The materiality of the data in question; and
- Any other information CMS deems relevant.[21]

In the commentary to the Final Rule, CMS indicates that "any decision to revoke will not be taken likely," and that the intention is to focus on "significant cases of non-reporting."[22]

It is somewhat common for providers and suppliers to report changes late when discovered after the legal reporting deadline. It will take time to determine the impact of this new "expanded" or "reorganized" rule on such occurrences; it is reasonable to expect that CMS will increase the frequency of enrollment revocations on this basis. What is clear is that providers and suppliers need to take seriously monitoring operational changes that are a part of the Medicare enrollment file and that all deliberate efforts should be made to report such changes timely.

3. CMS expands its enrollment enforcement authority in a host of additional enrollment areas.

In addition to the matters set forth above, CMS expands its enforcement authority in the Final Rule in a variety of other areas, including the following:

- Allowing the revocation of the enrollment of a physician or eligible professional who has a pattern or practice of ordering, certifying, referring, or prescribing Medicare Parts A or B services, items, or drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or otherwise fails to meet Medicare requirements;[23]

- Makes the following changes relative to the reenrollment bar that attaches to a provider or supplier that has had its enrollment revoked by:
    1. Increasing the length of reenrollment bars from three to ten years;
    2. Allowing an additional three-year reenrollment bar if CMS determines that the provider or supplier is attempting to circumvent its existing reenrollment bar by enrolling under a different name, numerical identifier, or business identity; and
    3. Allowing the imposition of a 20-year reenrollment bar if the provider or supplier is being revoked from Medicare a second time.[24]
    4. Applying a reapplication bar for prospective providers or suppliers for up to three years if the basis for the denial is false or misleading information or information omitted from an application to gain enrollment in Medicare (materiality is to be taken into account).[25]
- Allowing CMS to deny or revoke a provider or supplier's Medicare enrollment application if the provider or supplier is currently terminated or suspended from a state Medicaid program or another federal health care program, or if the provider or supplier's license is currently revoked or suspended (whether under the current or former names, numerical identifiers, or business identities);[26] and
- Updating the regulation governing enrollment moratorium to provide that it does not apply to any enrollment application that has been received by the Medicare contractor prior to the date the moratorium is imposed.[27]

Endnotes:

[1] Section 6401(a)(3) of the Affordable Care Act.
[2] CMS published the Final Rule on September 10, 2019 in the *Federal Register.* 84 Fed. Reg. 47794 (Sept. 10, 2019).
[3] 81 Fed. Reg. 10720 (Mar. 1, 2016).
[4] 42 C.F.R. § 424.502.
[5] 42 C.F.R. § 424.519.
[6] 42 C.F.R. § 424.502.
[7] 42 C.F.R.§ 424.519.
[8] *Id*.
[9] *Id.*
[10] *Id.*
[11] 42 C.F.R. § 424.530(a)(12); 42 C.F.R. § 424.535(a)(18).
[12] *Id.*
[13] 84 Fed. Reg. 47823.
[14] 42 CFR § 424.535(a)(20).
[15] *Id*.
[16] 84 Fed. Reg. § 47823-24.
[17] 42 C.F.R. § 424.535(a)(9).
[18] *See* 42 C.F.R. §424.516(d)(1)
[19] 42 C.F.R. § 424.535(a)(1).
[20] 84 Fed. Reg. 47829.
[21] 42 C.F.R. § 424.535(a)(9).
[22] 84 Fed. Reg. 47829-30.
[23] 42 C.F.R. § 424.535(a)(21).
[24] 42 C.F.R. § 424.535(c).
[25] 42 C.F.R. § 424.530(f).
[26] 42 C.F.R. § 424.530(a)(14) and §424.535(a)12).
[27] 42 C.F.R. § 424.570(a)(1)(iii).