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Guilt by Association – New Centers for Medicare and Medicaid Services Rule on Provider and Supplier Affiliations

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Over the past five years, Centers for Medicare and Medicaid Services (CMS) estimates that $20.7 billion in payments have been made to providers and suppliers involved in affiliations that present undue risk of fraud, waste, and abuse. Effective November 4, 2019, a new rule requires Medicare, Medicaid, and Children's Health Insurance Program (CHIP) providers and suppliers (collectively, "providers") to disclose certain affiliations with other providers and suppliers. CMS may deny enrollment to providers affiliated with previously sanctioned entities, even if those providers are not otherwise violating any rules. The new rule aims to reduce and prevent fraud risks, and CMS estimates that it will save $47.35 billion over the next 10 years.

Recognizing the burden that new affiliation disclosure requirements place on providers, the rule adopts a "phased-in" approach. Initially, CMS will begin by identifying providers who may have one or more affiliations and requiring further disclosures from them. These disclosures will not be required until CMS revises Form CMS-855 to accommodate same. CMS will then assess the phased-in approach and expand the process by additional rulemaking.

Under the rule, the definition of "affiliation" includes both ownership and reassignment relationships. Affiliation means:

- Five percent or greater direct or indirect ownership interest that an individual or entity has 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.
- Any reassignment relationship under 42 C.F.R. § 424.80.

An affiliation must be disclosed if it involves a provider or supplier that has one of the following "disclosable events":

- Currently has uncollected debt to Medicare, Medicaid, or CHIP (regardless of the amount of the debt, its repayment status, or its appeal status).
- Has been or is subject to a payment suspension under a federal health care program.
- Has been or is excluded from Medicare, Medicaid, or CHIP.
- Has had its Medicare, Medicaid, or CHIP billing privileges denied, revoked, or terminated.

If a provider had an affiliation with a provider or supplier in the past five years who at **any point in time** had a payment suspension, exclusion, denial, revocation, or termination of billing privileges, the affiliation must be disclosed. In determining whether an enrolling provider should have reported a disclosable event, CMS will use a reasonableness standard and require information to be reported if the disclosing provider or supplier knew or should reasonably have known of the event.

In light of the new rule, health care providers should make sure that they are affiliated with providers who have not been sanctioned and who have a robust billing and compliance program with regular audits, a compliance officer, and health law counsel. Failure to do so could put their Medicare, Medicaid, and CHIP enrollment at risk.

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