



**Center for Program Integrity**

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November 20, 2019

**Re: Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process (CMS-6058-FC)**

Dear State Medicaid Agency:

The Centers for Medicare & Medicaid Services (CMS) published a final rule with comment (CMS-6058-FC)<sup>1</sup> on September 10, 2019, that contains, in part, Medicaid and the Children's Health Insurance Program (CHIP) provisions regarding the reporting and evaluation of affiliations between entities in the Medicare, Medicaid, and CHIP programs. The affiliations provisions are part of the implementation of Section 1902(kk)(3) of the Social Security Act (the Act), as amended by Section 6401(b) of the Patient Protection and Affordable Care Act, which mandates that states require providers to comply with the same disclosure requirements established by the Secretary under section 1866(j)(5) of the Act.<sup>2</sup>

This letter presents a high level overview of the affiliations provisions that affect Medicaid and CHIP. The regulations, which can be found at 42 CFR Part 455 subpart B, became effective on November 4, 2019. In Part II of this letter, we discuss the affiliations reporting requirements for Medicaid and CHIP providers. **However, a State Medicaid Agency (SMA) is not required to request and collect disclosures of affiliations until after the SMA has completed the necessary updates to its Medicaid and CHIP provider enrollment applications (i.e., an affiliation disclosure section).**

**I. Affiliations and Disclosable Events**

CMS-6058-FC expands 42 CFR subpart B to include provisions requiring State Medicaid Agencies (SMAs) to collect from Medicaid and CHIP providers disclosures relating to certain current or past affiliations, arising through the individual provider or an owner or managing employee/organization, with another provider that has a disclosable event, as defined below.

Disclosable events include any of the following (42 CFR § 455.107(a)):

- A provider who currently has uncollected debt to Medicaid, CHIP, or Medicare

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<sup>1</sup> 84 FR 47794.

<sup>2</sup> Further, Section 2107(e)(1) of the Act, as amended by section 6401(c) of the Affordable Care Act, applies the requirements of section 1902(kk) of the Act, including the disclosure requirements, to CHIP.

- A provider who has been or is subject to a payment suspension under a federal health care program
- A provider who has been or is excluded by the HHS Office of Inspector General (OIG) from Medicare, Medicaid, or CHIP
- A provider who has had Medicare, Medicaid, or CHIP billing privileges denied, revoked, or terminated

For an affiliation to exist, the provider that the SMA is evaluating or an owner or managing employee/organization of that provider must have been, or must currently be in, one of several particular roles—within the previous five years—with a currently or formerly enrolled Medicare, Medicaid, or CHIP provider that had one of the disclosable events listed above. The roles are as follows (42 CFR. § 455.101):

- A 5 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 (including, for purposes of this paragraph, sole proprietorships), 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 payment assignment relationship under 42 CFR. § 447.10(g)

Below is a scenario to help illustrate an affiliation and a disclosable event.

In 2014, Clinic A was excluded by the HHS OIG—the exclusion of Clinic A is a disclosable event.. Dr. John Smith was the sole owner of Clinic A. In 2019, Clinic B submits an application for enrollment with a SMA and Dr. Smith is listed as one of several 5% or greater owner owners on the application. Dr. Smith's previous ownership in Clinic A is an example of an affiliation that must be reported by Clinic B under the new affiliation disclosure requirements.

As outlined in 42 CFR § 455.107, depending on the implementation option selected by the State (as discussed below), the disclosure requirements will apply either to all non-Medicare providers enrolling or revalidating in Medicaid or CHIP, or to all such providers only upon request from the SMA. In either case, providers subject to the disclosure requirement must disclose to the SMA any and all affiliations that it or any of its owning or managing employees or organizations has, or within the previous 5 years, had with a currently or formerly enrolled Medicare, Medicaid, or CHIP provider or supplier that has a disclosable event.

Disclosing providers must provide the following information, pursuant to 42 CFR § 455.107(c), about each disclosable affiliation:

- General identifying information about the affiliated provider or supplier, which includes the following:
  - Legal name as reported to the Internal Revenue Service or the Social Security Administration (if the affiliated provider or supplier is an individual)

- "Doing business as" name (if applicable)
- Tax identification number
- National Provider Identifier (NPI)
- Reason for disclosing the affiliated provider or supplier
- Specific data regarding the affiliation relationship, including the following:
  - Length of the relationship
  - Type of relationship
  - Degree of affiliation
- If the affiliation has ended, the reason for the termination

## II. Options for Implementation of the Affiliations Reporting Requirements

Each SMA, in consultation with CMS, must select one of two options for implementing the new affiliation disclosure requirements. Once a SMA has selected an option for implementation, the SMA is not permitted to change its selection.

### Option 1:

Under this option, a SMA must update its Medicaid and CHIP provider enrollment applications to include disclosure criteria to capture affiliations. Once the SMA has updated its applications, the SMA must collect affiliation disclosures from **all** Medicaid or CHIP-only providers (providers not enrolled in Medicare) upon enrollment or revalidation.

### Option 2:

Under this option, a SMA must update its Medicaid and CHIP provider enrollment applications to include disclosure criteria to capture affiliations. Once the SMA has updated its applications, the SMA may **request** and collect disclosures from any and all Medicaid or CHIP-only providers (providers not enrolled in Medicare) that may have at least one current or previous (within the last 5 years) affiliation with a currently or formerly enrolled Medicare, Medicaid, or CHIP provider or supplier with a disclosable event as identified by the SMA, in consultation with CMS, through internal data, investigation, or some other means.

**However, pursuant to 42 CFR § 455.107(b), SMAs may take action on a provider's enrollment prior to updating their applications if the SMA determines that action is necessary based on affiliation information identified by the SMAs through internal data, investigation, or some other means.** See more information under Part III below regarding enrollment determinations.

For Medicare, CMS is implementing a phased-in, risk-based approach that is similar to Option 2 above for SMAs. Medicare may request that a provider or supplier disclose all of its affiliations in cases where Medicare believes, based on internal data, investigation, or otherwise, that the provider or supplier has at least one current or previous affiliation with a provider or supplier with a disclosable event.

## III. Making an Enrollment Determination

Once affiliation data is reported to the SMA or the SMA becomes aware of an affiliation through a means other than a provider's reporting, the SMA must make a determination, in consultation with CMS, as to whether or not the affiliation poses an undue risk of fraud, waste, or abuse. CMS will clarify the nature of this required consultation in future sub-regulatory guidance. States may not deny or terminate any provider's enrollment pursuant to 42 C.F.R § 455.107(g) until this guidance has been issued and the required consultation with CMS has taken place. Additionally, CMS will share its policies for evaluating the undue risk factors detailed below, as pertains to Medicare, in the near future. If, in consultation with CMS, the SMA determines that the affiliation poses an undue risk of fraud, waste, or abuse, the SMA must, per 42 CFR § 455.107(g), deny or terminate the provider's enrollment in Medicaid and CHIP.

The SMA must consider the following factors, as well as any other evidence that the SMA, in consultation with CMS, deems relevant to its determination of whether or not an undue risk of fraud, waste, or abuse exists:

- The duration of the affiliation
- Whether the affiliation still exists and, if not, how long ago the affiliation ended
- The degree and extent of the affiliation
- If applicable, the reason for the termination of the affiliation

Regarding the affiliated provider's disclosable event, all of the following:

- 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 a denial, revocation, termination, exclusion, or payment suspension is involved, the reason for the disclosable event

If the disclosable event is an uncollected debt:

- The amount of the debt
- Whether the affiliated provider or supplier is repaying the debt
- To whom the debt is owed

SMAs may consider developing criteria in efforts to consistently evaluate the factors outlined above.

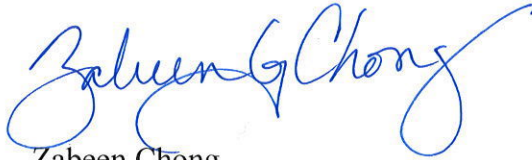
#### **IV. Dually Enrolled Providers**

SMAs are not required to collect disclosures of affiliations from providers who are also enrolled in Medicare as SMAs may rely on CMS to capture, review, and make the necessary determination on such disclosures. In determining if a provider is dually enrolled, the SMA must consult current CMS guidance at section 1.5.3.B.3 of the Medicaid Provider Enrollment Compendium (MPEC). This guidance provides SMAs with criteria for when it is appropriate to rely on Medicare's screening, which includes Medicare's enrollment determination based on the provider's disclosure of an affiliation(s).

#### **V. Additional Resources**

SMAAs may contact their designated Provider Enrollment Business Function Lead within the Provider Enrollment & Oversight Group in the Center for Program Integrity within CMS for further assistance in implementing these requirements. Additionally, we will continue to develop guidance and perform outreach with the SMAAs regarding affiliations. We thank you for your continued collaboration as we work to reduce fraud, waste, and abuse throughout the Medicaid and CHIP programs while protecting Medicaid and CHIP beneficiaries.

Sincerely,



Zabeen Chong

Director, Provider Enrollment and Oversight Group