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CMS finalizes new program integrity rules

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On September 10, 2019, the Centers for Medicare & Medicaid Services (CMS) published final rules on program integrity and provider enrollment.[1] With the intent of closing some gaps in the rules that currently keep CMS from denying or revoking enrollment of providers and suppliers, CMS estimates savings from the rule changes to be $47 billion over ten years.

Affiliation reporting

Among other changes, CMS may ask for affiliation information upon enrollment or revalidation. Affiliation[2] is defined as applying to the owning or managing employees and the organization and means any of the following:

1. A 5% or greater direct or indirect ownership interest that an individual or entity has in another organization;
2. A general or limited partnership interest (regardless of the percentage) that an individual or entity has in another organization;
3. 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;
4. An interest in which an individual is acting as an officer or director of a corporation; and
5. Any payment reassignment relationship.

For these employees and organizations, any relationship currently or within the past five years that meets the definition of a disclosable event must be reported on the form CMS-855 (the Medicare enrollment application).

Disclosable events include:

1. An uncollected debt (including overpayments and imposed civil monetary payments) to Medicare, Medicaid, or Children's Health Insurance Program (CHIP) (regardless of the amount of the debt, whether the debt is being repaid, and whether the debt is still under appeal);
2. Payment suspension or exclusion by Office of Inspector General (regardless of the reason for the exclusion, how long ago the suspension/exclusion was, or whether it is under appeal); and
3. Denial, revocation, or termination (including situations where the provider or supplier voluntarily terminated its enrollment to avoid a potential revocation or termination).

If your organization is selected by CMS, reporting on affiliations is required and must include the following information:

- Basic information (legal business name, "doing business as" name, tax identification number, national provider identification);

- The reason for reporting the affiliation; and
- Specific data on the affiliation relationship (length and type of the relationship, degree of affiliation, and, if the relationship has ended, the reason for the termination).

If the provider fails to fully and completely report the information required, the enrollment application may be denied to new providers, or the existing provider's enrollment may be terminated or revoked. Several commenters observed that the affiliate may not be forthcoming with the data or information, especially if the affiliation has been terminated. CMS responded that it would consider whether the provider knew or should have known of the disclosable event on a case-by-case basis. Also, CMS intends to issue subregulatory guidance on the affiliation disclosure process.

Factors CMS will consider in the assessment of undue risk of fraud, waste, and abuse include:

- Duration of the affiliation;
- How long the affiliation has existed or, if affiliation terminated, how long ago it was;
- Strength and scope of affiliation;
- If the disclosable event is an uncollected debt:
    - Amount of debt,
    - To whom the debt is owed, and
    - Whether the supplier or provider is paying the debt;
- The reason for the disclosable debt; and
- Any other evidence that CMS may consider relevant.

Medicaid and CHIP enrollment

States also will need to modify their Medicaid plans to select one of two options for requiring the disclosure of affiliation information. In the first option, all non-Medicare providers newly enrolling in Medicaid or CHIP must disclose any and all affiliations that they or any of their owning or managing employees have or, within the previous five years, had with a currently or formerly enrolled Medicare, Medicaid, or CHIP provider or supplier with a disclosable event. The second option is that the non-Medicare provider would supply the same information upon request from the state.

Revoked/opt-out practitioners

The rule change prohibits revoked or opt-out providers from ordering or certifying the need for services in the Medicare program. The rationale for this change was that these providers did not get the rigorous review associated with Medicare enrollment. One concern vocalized by a commenter was that there is no data available to providers to determine when a provider is opt-out or revoked. CMS responded by saying it would look at ways to expand the scope of revocation data as the rule unfolds.

Documentation requirements

Documentation by a provider or supplier under Parts A and B of Medicare must be maintained for seven years. Additionally, the ordering, prescribing, or certifying physician or non-physician practitioner must maintain records demonstrating the need for the service for seven years. The rule change specified that the information must be provided to CMS upon request, or the provider may face revocation of Medicare billing privileges.

Enrollment revocation

A provider's enrollment into Medicare may now be revoked by CMS for any of these reasons:

- Failure to report certain information to CMS in a timely manner;
- Termination from other programs (e.g., Medicaid);
- Debt referred to the U.S. Department of the Treasury;
- Previous revocation under different name or numerical or business identifier;
- Affiliation that CMS determines is undue risk;
- Billing from a noncompliant location; and/or
- Abusive ordering, certifying, referring, or prescribing of Part A or B services, items, or drugs.

Once enrollment has been revoked, a provider can be prohibited from re-enrolling in Medicare for up to ten years. If CMS determines that a provider/supplier is trying to circumvent the enrollment ban, it can add additional time to the ban on re-enrollment. Additionally, if an organization has its Medicare enrollment revoked the second time, the prohibition on re-enrollment may be extended to a 20-year period. CMS can also revoke all enrollments, regardless of type, associated with a provider, regardless of name or business identifier.

Moratorium

The rule clarifies that a temporary moratorium imposed in a geographic area would not affect applications received by the Medicare contractor before the moratorium was imposed. Similarly, the moratorium would not affect changes in ownership or address information (unless the provider/supplier proposed to move to inside the geographic area of the moratorium from outside).