Memorandum

OIG/GSA Exclusion Screening Requirements for Accountable Care Organizations under the Medicare Shared Savings Program and ACO REACH Model

WILEMS resource group

Overview

The Office of Inspector General's (OIG) List of Excluded Individuals/Entities (LEIE) provides information to the health care industry, patients and the public regarding individuals and entities currently excluded from participation in Medicare, Medicaid and all other Federal Health Care Programs. Individuals and entities who have been reinstated are removed from the LEIE. The scope of an exclusion under Title 11 of the Social Security Act is from all Federal Health Care Programs, as defined in 42 CFR 1001.2. Federal Health Care Programs include Medicare, Medicaid, and all other plans and programs that provide health benefits funded directly or indirectly by the United States (other than the Federal Employees Health Benefits Plan).

The effect of an exclusion is that no payment will be made by any Federal Health Care Program for any items or services furnished, ordered or prescribed by an excluded individual or entity. No program payment will be made for anything that an excluded person furnishes, orders, or prescribes. This payment prohibition applies to the excluded person, anyone who employs or contracts with the excluded person, any hospital or other provider for which the excluded person provides services, and anyone else. The exclusion applies regardless of who submits the claims and applies to all administrative and management services furnished by the excluded person.

In May of 2013 the OIG released an updated Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs[1]. The Advisory Opinion clarifies that if a health care provider arranges or contracts (by employment or otherwise) with someone they know, or **should** know, has been excluded, then that provider can be fined up to $10,000 for each item or service provided by the excluded individual, as well as an assessment of up to three times the amount claimed. The provider can also face program exclusion.

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[1] OIG Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs; https://oig.hhs.gov/exclusions/files/sab-05092013.pdf

How do the Advisory Opinion and other regulations contribute to a Medicare Accountable Care Organization's (ACO) responsibility to conduct OIG/GSA screenings?

Requirement to Conduct Exclusion Screenings

Based on this Advisory Opinion, there can be little doubt that the Participants, Provider/Suppliers and Preferred Providers should be screening all individuals or entities providing services within their organizations. Since ACOs are still relatively new, there may be some question (and push back) as to whether this Advisory Opinion applies.

Section 425.208(b) of the Medicare Shared Saving Program Final Rule and Section 15.04 of the ACO REACH Model Participation Agreement require the ACO to comply with, and to require all individuals or entities performing functions or services related to ACO activities to comply with all applicable laws, regulations and guidance, including, but not limited to: (a) federal criminal laws; (b) the False Claims Act; (c) the anti-kickback statute; (d) the civil monetary penalties law; and (e) the physician self-referral law. The specificity of this requirement creates a burden to ensure compliance with each of the above laws and thus, a requirement to monitor compliance. Moreover, ACOs receive funds and operate under Medicare, which is clearly included in Federal Health Care Programs. Therefore, Wilems Resource Group, LLC recommends that all Medicare Shared Savings Program and REACH ACOs build a process to conduct OIG/GSA screenings on ACO-related individuals.

Frequency of Exclusion Screenings

Most organizations acknowledge the requirement to conduct screenings, and do so upon hire or contracting, but few take any steps to conduct screenings after that point. The OIG updates the LEIE on a monthly basis and healthcare entities are instructed to check them "periodically". The completion of this screening speaks to whether the organization "knew or should have known" that the individual was excluded for purposes of imposing Civil Monetary Penalties under the False Claims Act. The Federal Department of Health and Human Services has stated that organizations should check the listing monthly, as this is what is "reasonable" for when the organization should have known that the individual was excluded.

State and Federal programs have repeatedly taken the position that the checks should be performed on a monthly basis. CMS has also released a memo stating that monthly checks should be required for State Medicaid programs. While this analysis was done in response to a question for the Medicaid program, it holds true for all Federal Health Care Programs (including the Shared Savings Program and ACO REACH Model). CMS has even taken the step to include this requirement in Chapter 21 of the Medicare Managed Care Manual stating:

> "**Monthly** screening is essential to prevent inappropriate payment to providers, pharmacies, and other entities that have been added to the exclusion lists since the last time the list was checked. After entities are initially screened against the entire LEIE and EPLS as the time of hire or contracting, sponsors need only review the LEIE supplement file provided each month, which lists the entities added to the list that month and review the EPLS updates provided during the specified monthly time frame." (emphasis added)."

Recommendation for Medicare ACOs

As a result, while there is no specific requirement in the Medicare Shared Savings Program Final Rule, or in the ACO REACH Model Participation Agreement for the screening to be completed monthly, Wilems Resource Group recommends that all Shared Savings Program and REACH ACOs complete the screening upon hire or contracting and monthly thereafter in order to avoid making payments to an individual or entity who has been excluded from federal health care programs and risking the imposition of Civil Monetary Penalties. Based on the opinions from the OIG and CMS, as well as our experience with CMS in these, and other programs for which CMS has oversight, Wilems Resource Group believes this is the expectation from CMS and the OIG.

How to Conduct an Exclusion Screening

Although there is much flexibility in the way an ACO chooses to develop a screening process, consider the following tips and recommendations:

Recommendations

- Create an ACO Compliance Policy that details the screening procedure and protocol for non-compliance.
- Choose a designated ACO team member (Designee) to "own" the process. They will be responsible for downloading the LEIE Database file, communicating with the ACO Participant TINS or any entity performing functions/services related to the ACO, and maintaining a tracking log of exclusion screening confirmations.

Tips

- Determine a location (e.g. SharePoint folder) and naming convention to house the LEIE Database downloads and corresponding trackers.
- The most recent Updated LEIE Database can be downloaded from the OIG website (https://oig.hhs.gov/exclusions/exclusions_list.asp).
    - How to download the database:
        - Locate hyperlink to CSV file under "LEIE Database"
        - Right-click the file link
        - If using IE, choose "Save target as…"
        - If using Chrome or Firefox, choose "Save link as…"
        - Save file in OIG Exclusion Database <location>
- If the ACO only has a few individuals to screen, the OIG website (https://exclusions.oig.hhs.gov/) provides an opportunity to easily search for individuals or entities.