

SOMEWHERE BEYOND THE OIG

Discussion of Exclusion Checks

Your Hosts

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Introduction to Exclusions

Exclusions Program

OIG has the authority to exclude individuals and entities from Federally funded health care programs.

Exclusions Program

Online Searchable Database

LEIE Downloadable

<https://oig.hhs.gov/exclusions/>

Monthly Supplement

This webpage provides

the authority to exclude

individuals and entities

from Federally funded

health care programs.

Those that are excluded

are prohibited from

participating in

OIG has the authority to exclude individuals and entities from Federally funded health care programs pursuant to section 1128 of the Social Security Act (Act) (and from Medicare and State health care programs under section 1156 of the Act) and maintains a list of all currently excluded individuals and entities called the List of Excluded Individuals/Entities (LEIE). Anyone who hires an individual or entity on the LEIE may be subject to civil monetary penalties (CMP).

The primary effect is that no payment will be made for any items or services furnished, ordered, or prescribed by an excluded individual or entity. This includes Medicare, Medicaid, and all other Federal plans and programs that provide health benefits funded directly or indirectly by the United States (other than the Federal Employees Health Benefits Plan).

Introduction to Exclusions

A provider could be subject to CMP liability if an excluded person participates in any way in the furnishing of items or services that are payable by a Federal health care program.

To avoid potential CMP liability, providers should check the LEIE prior to employing or contracting with persons and periodically check the LEIE to determine the exclusion status of current employees and contractors.

UPDATED

Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs

Issued May 8, 2013

But, wait, there's more

- General Services Administration, System for Award Management (GSA/SAM) – federal procurement database for the government, which contains information on exclusions/ineligibilities/debarments from doing business with federal government agencies and/or programs, like HUD, FDA, SNAP, DOT, DOL, FEMA, etc.
- FDA/ORA for Clinical Investigators
- DHHS/PHS Office of Research Integrity
- Dept of Commerce, Bureau of Industry & Security Denied Persons
- Dept of Treasury, Blocked Persons List (Terrorism)
- TriCare Exclusion List
- “Most Wanted” Lists for Various Federal Agencies



But, wait, there's even more

Some States maintain their own exclusion lists, pursuant to 42 CFR section 1002.210 or State authority, which include individuals and entities whom the State has barred from participating in State government programs. **States with such lists should remind providers that they are obligated to search their State list routinely whenever they search the LEIE.**

Also, the ACA requires States to terminate a provider's participation in their respective State Medicaid programs if that provider is terminated for cause (i.e., for reasons of fraud, integrity, or quality) from another State Medicaid program. However, this is not a direct requirement on providers, and is not fully implemented.

<https://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SMD011609.pdf>
<https://oig.hhs.gov/oei/reports/oei-06-12-00030.pdf>



Discussion of Who Do you Screen

- Employees – who is considered an “employee”?
- Contractors – can contract with the vendor to screen contractors provided, but where does CMP liability lie?
- Medical Staff – may also include non-physician providers
- Vendors - Items or equipment sold by an excluded manufacturer or supplier, used in the care or treatment of recipients and reimbursed, *directly or indirectly*, by a government program.

Discussion of Who Do you Screen

- Referring Providers – if you accept orders for diagnostic/therapeutic services from providers that are not on medical staff, you still have to check their exclusion status. But when?
- Governing Board - if an individual has a 5% or more controlling interest in an organization and is an excluded individual, the organization will be subject to CMPs. An organization with a 20 (or less) member board would have members with a 5% or greater controlling interest.
- Subsidiary Business Units – if your organization acquires healthcare business units, you may want to search the names of those separate units to ensure they do not appear on any exclusion lists.

***WHAT DO
YOU DO
WITH AN
EXCLUSION?***



*What do you do
with an
Exclusion?*

What is the Source?

- Exclusions on the OIG/LEIE
 - A nurse trainee only attended a day of orientation and had no patient contact – is this reportable?
 - Would it matter more if they attended a week of training? Or a month? Or two months?
 - Would it matter more if they had patient contact with an instructor? Without an instructor?
 - May still have to pay them under state employment laws.
 - A records scanner worked for a month with no direct patient contact – is this reportable?
 - Would it matter if they worked in a hospital versus in a corporate office versus worked from home?

*What do you do
with an
Exclusion?*

What is the Source?

- Excluded through the GSA/SAM database (not on OIG)
 - Does the sanction affect federal healthcare reimbursement?
 - Dept of Labor for faulty employment practices
 - FDA/ORA for improper research practices
 - SNAP for food stamp fraud
 - HUD for inappropriate landlord/tenant practices
 - Need to contact the agency that imposed the sanction to determine the scope and impact.

*What do you do
with an
Exclusion?*

What is the Source?

- State Medicaid Exclusions (not on OIG)
 - Do you have a State Medicaid Number for that state and receive Medicaid reimbursement from that state?
 - What does the state require of you in terms of monitoring and reporting exclusions?
 - If you only receive a small amount of reimbursement from that state, what steps can you take to analyze your risk?
 - Pull all claims to that state's Medicaid to see if the excluded party was involved
 - Do you report non-compliance to the OIG?
 - Can be disclosed to state Medicaid program or to the OIG. OIG can resolve liability on behalf of the Medicaid program.

*What do you do
with an
Exclusion?*

Who is Excluded?

Employees

There is control over the interview process and whether the person will have to be terminated.

- Almost definitely terminated for an OIG exclusion
- May depend on risk tolerance if other exclusion

Is there a gap in the process?

- Corrective Action Plan should involve a review of:
 - *Background check process*
 - *Exclusion check process*
 - *Did the employee lie about the exclusion?*
 - *Was there a sooner point in which the exclusion could have been discovered?*

*What do you do
with an
Exclusion?*

Who is Excluded?

- Examples of Excluded Employees
 - The prohibition on Federal health care program payment for items or services furnished by an excluded individual goes **beyond direct patient care**. Excluded individuals are prohibited from furnishing administrative and management services that are payable by the Federal health care programs.
 - For example, an admission specialist at an assisted living facility, a health system patient scheduler, the office manager of a chiropractic practice, and a health system eligibility clerk.

*What do you do
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Exclusion?*

Who is Excluded?

Medical Staff

- Many of the same considerations as with employees (a degree of control with interviews and dismissal).
- However, there is definitely contact with patients, so the exposure is significantly increased.
- Do you have a separate office/department that deals specifically with Medical Staff – what is their role in detecting exclusions?
- Was there a violation of Bylaws by the excluded person?

*What do you do
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Exclusion?*

Who is Excluded?

Medical Staff

- Usually subject to more scrutiny through the credentialing process, so “surprise” exclusions are rare.
- Even though a member of a hospital’s medical staff is not paid by the hospital, the hospital may still be subject to CMP liability if the hospital is paid by the Federal health care programs for items or services **furnished, ordered, or prescribed** by the excluded physician.

*What do you do
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Exclusion?*

Who is Excluded?

Vendors/Contractors

- Were the items/services contracted for a one-time shot, or are they ongoing?
 - Compare dates of exclusion to time of contract.
- Whose responsibility was it to ensure exclusion status?
- How do you ensure that this vendor/contractor is not used again?
 - What system controls are in place to stop payment or stop entry as a new vendor?

*What do you do
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Exclusion?*

Who is Excluded?

Vendors/Contractors

- Contracts with staffing agencies should be clear about who bears the responsibility for exclusion screening.
- A facility may be found liable for CMPs for submitting claims to Federal health care programs for items or services furnished by an excluded nurse under a contract with a staffing agency.
- The facility may reduce or eliminate its liability if facility is able to show it “reasonably relied” on the staffing agency to perform a check of the LEIE.
- In November 2018, a university medical center paid just over \$250,000 to resolve its liability for items and services furnished by an RN engaged through a staffing agency.

*What do you do
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Exclusion?*

Who is Excluded?

Referring Providers

- Does your facility accept orders for outpatient diagnostic/therapeutic services from providers who are not credentialed by the facility?
- How do you monitor for excluded providers?
 - Before providing services?
 - Do you have a process for reviewing when orders are placed to see when a new exclusion check should occur?
- If you discover a referring provider is excluded, how do you communicate with them that you will no longer accept their orders?
- For a State Medicaid exclusion for a referring provider, how do you calculate risk?

*What do you do
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Who is Excluded?*

Referring Providers

- Like Medical Staff: ...the hospital may still be subject to CMP liability if the hospital is paid by the Federal health care programs for items or services **furnished, ordered, or prescribed** by the excluded physician.
- These are sometimes the most difficult to control, since the service may be provided “at random” – a patient just shows up with an order.
- The CMP liability potential is usually minimal, since the services are minimal, but a risk nonetheless.

**WHO DO
YOU
WORK
WITH?**



Who Do you Work With?

- Human Resources – to get a list of employees to screen, and to work through any exclusion results that may require interviews or termination.
- Onboarding – to make sure exclusion checks are performed and reviewed properly
- Medical Staff Services/Credentialing – similar to HR
- Purchasing/Supply Chain – similar to HR

Who Do you Work With?

- Accounts Payable – if no separate purchasing/supply chain department, to determine who the vendors are
- Registration – what safeguards are in place to make sure we do not perform services at the direction of an excluded provider?
- Billing – how to stop a claim if an excluded provider is discovered?



How do you report an exclusion?

UPDATED

OIG's Provider Self-Disclosure Protocol

Note: This notice, issued on April 17, 2013, updates the Provider Self-Disclosure Protocol.

The screenshot shows the 'REPORT FRAUD' website for the Office of Inspector General, U.S. Department of Health & Human Services. The page title is 'Provider Self-Disclosure Protocol'. It includes a 'Self-Disclosure Online Submission' button, a 'Current Information' section with links to various notices, and an 'EXCLUSIONS DATABASE' and 'REPORT FRAUD' logo.

How do you report an exclusion?

- OIG's Self Disclosure Protocol has specific guidelines for the information to be reported in disclosures involving the employment of an excluded individual.
 - Identity
 - Job Duties
 - Dates of Employment
 - Description of background checks performed
 - Description of entity's screening process
 - How was conduct discovered
 - What corrective action was taken
- Before disclosing, should screen all current employees and contractors against the LEIE.
- Damages may be based on Federal payor mix percentage of salary and benefits if services not separately billed.

***HOW DO YOU
MAKE
EXCLUSION
CHECKS PART
OF YOUR
COMPLIANCE
PROGRAM?***



*Exclusion
Checks as
part of your
Compliance
Program*

1. **Policies/Procedures** – maintain detailed procedures about how data is gathered, reviewed, and audited.
2. **Oversight** – reporting exclusion hits to governing authority of organization through Chief Compliance Officer.
3. **Education** – create materials for audience-specific presentations, that explain why exclusion checks are important and how they are part of the process.
4. **Communication** – make other key departments aware that exclusion information needs to be reported to Compliance.

*Exclusion
Checks as
part of your
Compliance
Program*

5. **Auditing/Monitoring** – are lists submitted for monthly checks accurate and complete? Are new entries added timely?
6. **Disciplinary action** – if someone was responsible for checking an exclusion and missed it, policies should outline a course of action.
7. **Corrective Action** – who is activated when an exclusion hit occurs and what documentation is needed to investigate?



Resources Available

