Exclusions FAQ: Answers to Questions Concerning Exclusions

What authority does OIG have to exclude individuals or entities? Are there different types of exclusions?

OIG imposes exclusions under the authority of sections 1128 and 1156 of the Social Security Act (Act). A list of all OIG exclusions and their statutory authorities can be found on the Exclusion Authorities page.

What is OIG's Administrative Process for Imposing Exclusions?

Summary:

OIG's exclusions process is governed by regulations that implement sections of the Act. When an individual or entity gets a Notice of Intent to Exclude (NOI), it does not necessarily mean that they will be excluded. OIG will carefully consider all material provided by the person who received the NOI before making a decision. All exclusions implemented by OIG may be appealed to an HHS Administrative Law Judge (ALJ), and any adverse decision may be appealed to the HHS Departmental Appeals Board (DAB). Judicial review in Federal court is also available after a final decision by the DAB.

Details:

When OIG is considering excluding an individual or entity under section 1128 of the Act, the administrative process is governed by regulations codified at 42 CFR sections 1001.2001 through 1001.2007. The process varies somewhat, depending upon the basis for the proposed exclusion.

For all proposed mandatory exclusions (sections 1128(a)(1)-(4) of the Act) that are longer than the mandatory minimum five-year period, and most proposed permissive exclusions (sections 1128(b)(1)-(b)(5), (b)(8)-(b)(11), and (b)(14)-(b)(15), and (b)(16) of the Act), the administrative process is the same. OIG sends out a written NOI to any individual that we are considering excluding. The NOI includes the basis for the proposed exclusion and a statement about the potential effect of an exclusion.

The NOI is pre-decisional and allows the individual or entity 30 days to respond in writing with any information or evidence relevant to whether the exclusion is warranted and to raise any other related issues, such as mitigating circumstances. OIG considers all available information in making a final decision about whether to impose the exclusion.

If we decide to proceed with exclusion, we send the individual or entity a Notice of Exclusion along with information about the effect of the exclusion and appeal rights. For mandatory exclusions that are for the minimum five year period, we may not send a NOI. For these exclusions, a Notice of Exclusion is the first notification sent. Exclusions are effective 20 days after the Notice of Exclusion is mailed, and notice to the public is provided on OIG's website. The exclusion may be appealed to an ALJ, and any adverse decision may be appealed to the DAB. Judicial review is also available after a final decision by the DAB.

When a permissive exclusion is being considered under section 1128(b)(6) of the Act, the NOI allows the individual or entity to request an opportunity to present oral argument to an OIG official before a decision about whether to exclude is reached. This is in addition to the right to submit documentary evidence and written argument.

If OIG decides to proceed with exclusion, we send the individual or entity a Notice of Exclusion and the subsequent administrative process is identical to the one described above. When a permissive exclusion is imposed under sections 1128(b)(12) or (b)(13) of the Act, OIG is not required to send a NOI. We send the individual or entity a Notice of Exclusion along with information about the effect of the exclusion and appeal rights. An exclusion under section 1128(b)(12) is effective immediately and an exclusion under section 1128(b)(13) is effective 20 days after the Notice of Exclusion is mailed, and notice to the public is provided on OIG's website. The subsequent administrative process is identical to the one described above.

When OIG is considering excluding an individual or entity under section 1128(b)(7) of the Act, the administrative process differs from that described above. OIG will send the individual or entity a written Notice of Proposal to Exclude. The written notice will include the basis for the proposed exclusion, the length of the exclusion, the factors we considered in setting the exclusion period, the effect of the exclusion, the earliest date on which OIG will consider a request for reinstatement, appeal rights and reinstatement information. The individual or entity may file a written request for a hearing within 60 days of receipt of the Notice of Proposal to Exclude. If the individual or entity does not request a hearing, the exclusion goes into effect 60 days after the receipt of the Notice of Proposal to Exclude. If the individual or entity makes a timely written request for a hearing, and OIG has determined that the health or safety of individuals receiving services under Medicare or any State health care program does not warrant immediate exclusion, an exclusion will only go into effect as of the date of the ALJ's decision, if the ALJ upholds OIG's decision to exclude. Any adverse decision may be appealed to the DAB, and judicial review is available after a final decision by the DAB.

If OIG excludes an individual under section 1156 of the Act, OIG will send a written notice notifying the individual of the exclusion. The written notice will include the legal and factual basis for the exclusion, the length and effective date of the exclusion, the effect of the exclusion, appeal rights, reinstatement information, and patient notification option. The exclusion goes into effect 20 days after the date of the written notice. The individual may file a written request for a hearing before an ALJ within 60 days of receipt of the written notice. Any adverse decision by the ALJ may be appealed to the DAB, and judicial review is available after a final decision by the DAB.

An individual excluded under section 1156 of the Act may request a preliminary hearing if the location where services are rendered to over 50 percent of the individual's patients at the time of the written notice is in a rural health professional shortage area or in a county with a population of less than 70,000. Such an individual may file a written request for a preliminary hearing before an ALJ within 15 days of receipt of the written notice. A request for a preliminary hearing will stay the effective date of the exclusion pending the ALJ's decision at the preliminary hearing. A request for a preliminary hearing received after the 15-day period has expired will be treated as a request for a hearing before an ALJ as described in the paragraph above.

What is the scope and effect of a section 1128 exclusion?

The scope of an exclusion under section 1128 of the 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). For exclusions implemented before August 4, 1997, the exclusion covers only the following Federal health care programs: Medicare, Medicaid, Maternal and

Child Health Services Block Grant, Block Grants to States for Social Services, and State Children's Health Insurance programs. Federal health care program exclusions do not reach other Federal programs (although HHS or another Federal agency could separately initiate a suspension or debarment of an excluded person from other Federal procurement or nonprocurement programs).

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. 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.

There is a limited exception to this payment prohibition for the provision of certain emergency items or services not provided in a hospital emergency room. See 42 CFR 1001.1901(c).

Additional information is available in the Updated Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Programs.

What is the scope and effect of a section 1156 exclusion?

The scope of an exclusion under section 1156 of the Act is from Medicare and all State health care programs as defined in section 1128(h) of the Act. Exclusions under section 1156 of the Act do not reach other Federal programs (although HHS or another Federal agency could separately initiate a suspension or debarment of an excluded person from other Federal procurement or nonprocurement programs).

The effect of an exclusion is that no payment will be made by Medicare or any State health care program for any items or services furnished, ordered or prescribed by an excluded individual or entity. 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.

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When were exclusions first implemented?

OIG has been implementing exclusions since about 1981, but the Department of Health & Human Services first began imposing them in 1977.

Does an exclusion affect a person's right to receive benefits under the Medicare, Medicaid and all Federal health care programs?

No. An exclusion affects only the ability to claim payment from these programs for items or services rendered; it does not affect the ability to receive benefits under the programs.

Does an OIG exclusion affect an individual's or entity's ability to participate in a real estate transaction involving Department of Housing and Urban Development (HUD) financing?

No. The statutory authority for OIG's exclusion actions does not prohibit an individual or entity who has been excluded by OIG from participating in any capacity (e.g., buyer, seller, real estate agent, loan processor) in real estate transactions that involve HUD financing. OIG has no authority to make determinations regarding an individual's or entity's eligibility to participate in a transaction that involves HUD financing; those determinations are made by HUD.

The effect of an OIG exclusion, and appearance on the General Services Administration's System for Award Management (SAM) website as a result of such exclusion, is that no payment will be made by any Federal health care program for items or services furnished, ordered, or prescribed by the excluded individual in any capacity.

Any questions regarding this issue should be directed to HUD via email at answers@hud.gov or by telephone at (800) CALL-FHA (225-5342).

What is a waiver?

OIG has the authority to waive an individual's or entity's exclusion from participation in Federal health care programs. More information on waivers and a list of waivers currently in effect is available on our website.

What is the effect of an exclusion waiver on payment?

When OIG grants a waiver to an excluded individual or entity, it permits payment by Medicare, Medicaid, and all other Federal health care programs for items and services that they furnish, order, or prescribe, within the scope of the waiver (e.g., within a specified geographic location or institution, limited to a specific medical specialty, etc.). It is important to note that the waiver means that, within the scope identified in the waiver letter, Federal health care programs will pay for (1) covered services, such as office visits, home visits, and hospital visits, furnished by the physician or other health care provider, (2) hospital stays, medical tests, procedures, and/or equipment ordered by the physician or other health care provider, and (3) drugs, devices, and/or other items prescribed by the health care provider.

How does an excluded individual or entity get reinstated?

Reinstatement of an excluded individual or entity is not automatic once the specified period of exclusion ends. In order to participate in Medicare, Medicaid and all other Federal health care programs once the term of exclusion ends, the individual or entity must apply for reinstatement and receive written notice from OIG that reinstatement has been granted.

An individual or entity with a defined period of exclusion (e.g., 5 years, 10 years, etc.) may begin the process of reinstatement 90 days before the end of the period specified in the exclusion notice letter. Requests received earlier than 90 days before the end of the period of exclusion will not be considered.

An individual or entity excluded under section 1128(b)(4) of the Act, whose period of exclusion is indefinite, may apply for reinstatement when they have regained the license referenced in the exclusion notice. In addition, under some conditions an individual or entity excluded under section 1128(b)(4) of

the Act may apply for reinstatement if they (1) have obtained a different health care license in the same state, (2) have obtained any health care license in a different state, or (3) do not possess a valid health care license of any kind in any State but have been excluded for a minimum period of 3 years. Additional information regarding the requirements for early reinstatement is available at 42 CFR 1001.501(b)-(c).

Obtaining a provider number from a Medicare contractor, a State health care program or a Federal health care program does not reinstate an individual's or entity's eligibility to participate in those programs. Additional information regarding the reinstatement process is available at 42 CFR 1001.3001-3005.

To apply for reinstatement, an excluded individual or entity must send a written request which contains the individual's or entity's full name (if excluded under a different name, please also include that name), date of birth for an individual, telephone number, email address and mailing address. The request can be faxed or emailed to the OIG. The fax number and email address are below.

Fax: (202) 691-2298

Email: sanction@oig.hhs.gov

For purposes of the exclusion authority in section 1128(b)(8) of the Social Security Act (SSA), does an "immediate family member" include the lawfully married same-sex spouse of a person and family members that result from the lawful marriage of same-sex individuals?

Yes. Section 1128(j)(1) of the Act and the regulations at 42 CFR 1001.1001(a)(2) define the term "immediate family member" to mean the person's:

- Husband or wife;
- Natural or adoptive parent, child, or sibling;
- Stepparent, stepchild, stepbrother or stepsister;
- Father-in-law, mother-in-law, daughter-in-law, son-in-law, brother-in-law, or sister- in-law;
- Grandparent or grandchild; and
- Spouse of a grandparent or grandchild.

In United States v. Windsor, 570 U.S. __, 113 S. Ct. 2675 (2013), the Supreme Court ruled that section 3 of the Defense of Marriage Act is unconstitutional. In light of this decision, the Department has instituted a policy of treating same-sex marriages on the same terms as opposite-sex marriages to the greatest extent reasonably possible. This FAQ clarifies Windsor's application to the exclusion authority under section 1128(b)(8) of the Act. Effective June 26, 2013, the date of the Windsor decision, same-sex spouses and family members that result from same-sex marriages meet the definition of "immediate family member" if the state or other jurisdiction, whether foreign or domestic, where the couple was married recognizes the marriage under its laws, or if the state(s) or other jurisdiction(s) where the couple lives recognizes the marriage as a legally valid marriage. Any transfer of ownership or control interest in anticipation of or following a person's conviction, assessment, or exclusion (as described in section 1128(b)(8)(A)(iii) of the Act) that is made on or after June 26, 2013 is subject to this policy.

What is the process for reporting fraud or abuse related to the Medicare and Medicaid programs?

See the contact information on the OIG Hotline page.

What is the contact information for exclusions?

Email: sanction@oig.hhs.gov

Answers to Questions Concerning the List of Excluded Individuals/Entities (LEIE)

What is the LEIE?

OIG's 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.

What is the data format for the LEIE?

The LEIE is available in two formats:

The Online Searchable Database enables users to enter the name of an individual or entity and determine whether they are currently excluded. If a match is made on an individual, the database can verify with an individual's Social Security Number (SSN) that the match is unique. Employer Identification Numbers (EINs) are available for verification of excluded entities.

The Downloadable Database enables users to download the entire LEIE to a personal computer. Supplemental exclusion and reinstatement files are posted monthly to the OIG's website, and these files can be merged with the previously downloaded data file to update the list. Users who do not wish to rely on the supplements to keep the information updated can download the Downloadable Data File each month.

Profile updates (changes to information on specific excluded individuals and entities) are also available on the Downloadable Database file web page.

Note: The Downloadable Database does not contain SSNs or EINs. Therefore, verification of specific individuals or entities through the use of the SSN or EIN must be done via the Online Searchable Database.

What is the most efficient way to search the LEIE?

For searching a few individuals or entities, consider using the Online Searchable Database. It allows for a search of up to five names at one time and to verify identities using an SSN or EIN.

For searching a large number, consider downloading the entire list via the LEIE Downloadable Database and using a spreadsheet or database program to perform searches.

Note: The Downloadable Database does not contain SSNs or EINs. Therefore, verification of specific individuals or businesses through the use of the SSN or EIN must be done via the Online Searchable Database.

When is the LEIE updated with new information?

Both versions of the LEIE are generally updated by the middle of each month. The updates include all actions taken during the prior month.

Can you notify me when the LEIE is updated?

A link for email updates, including notifications when the LEIE is updated, is on the botttom of every web page.

What should I do if I receive a positive match on an LEIE search?

Check the Updated Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs for guidance. If you have already employed the individual, check the Self-Disclosure Protocol.

Why is there a field to verify using SSNs on the Online Searchable Database, but the SSNs are not available in the Downloadable Data File?

The Privacy Act prohibits disclosing SSNs, so they cannot be included in the Downloadable Database. However, the Online Searchable Database uses the SSN input by the user as one of the matching criteria. It does not supply SSNs to users. Downloadable Database users who have a possible match on an individual or entity and want to verify with an SSN or EIN should use the Online Searchable Database's SSN and EIN feature to verify an identity.

What is an NPI?

The NPI (National Provider Identifier) has replaced the UPIN (see question below) as the unique number used to identify health care providers. The Centers for Medicaid & Medicare Services first began assigning NPIs in 2006, and providers were required to use NPIs as of mid-2008.

Why do some LEIE records not contain NPIs, and which records include NPIs?

Many individuals and entities that are excluded by OIG do not have NPIs to include in the LEIE. For those individuals and entities that have NPIs, OIG has added that information to records starting in 2008 and has included NPIs in the LEIE since that time.

What is a UPIN?

The UPIN (Unique Physician Identification Number) was established by the Centers for Medicare & Medicaid Services as a unique provider identifier in lieu of the SSN. UPINs were assigned to physicians as well as certain non-physician practitioners and medical group practices. CMS no longer maintains the UPIN registry.

What does it mean if the DOB, UPIN, NPI, SSN or EIN isn't in the LEIE?

If a search result does not contain a DOB (date of birth), UPIN (unique physician identification number), NPI (national provider identifier), SSN (Social Security number), or EIN (Employer Identification Number), it is not available from OIG. Contact the Exclusions Branch to determine if there is any other information available.

Does the LEIE include actions taken by other agencies?

No, the LEIE includes only exclusion actions taken by OIG.

What is the difference between the LEIE and the General Services Administration's (GSA) System for Award Management (SAM) website?

GSA administers SAM, which contains debarment actions taken by various Federal agencies, including exclusion actions taken by OIG. The LEIE contains only the exclusion actions taken by OIG. You may access SAM at https://www.sam.gov.

Why are there providers in the LEIE who are not included in the NPDB Public Use File?

The LEIE is a complete list of all currently excluded individuals and entities that have been excluded by OIG pursuant to sections 1128 and 1156 of the Social Security Act. The NPDB's Public Use File contains NPDB data specified under Titles IV of Public Law 99 660 and Section 1921 of the Social Security Act.

The criteria for inclusion in the NPDB are different than the criteria for inclusion in the LEIE. As a result, the records of many individuals and entities excluded by OIG are not contained in the NPDB Public Use File. For example, a DME business owner that has been excluded by OIG and included in the LEIE will not be found on the NPDB Public Use File.

Why are there providers in the NPDB who are not included in the LEIE?

The LEIE contains all individuals and entities that are currently excluded. Once an individual or entity has been reinstated, they are removed from the LEIE. In contrast, the NPDB contains information on both exclusions and reinstatement actions taken by OIG. Further, the NPDB contains records on additional providers who have not been excluded by OIG and therefore would not appear in the LEIE.

How can I obtain a copy of an individual's or entity's exclusion notice?

Submit a written request via email or fax with a screenshot or attachment from the LEIE identifying the individual or entity. Requests without a screenshot or attachment from the LEIE will be insufficient. Generally, the only documentation available is the exclusion notice that informs the subject of the exclusion and its basis, its effect and the subject's appeal rights. If the subject has been reinstated, the reinstatement notice may also be available.

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