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Complete Healthcare Compliance Manual 2024
Exclusion from Federal Healthcare Programs

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Fast Facts

Title of law: Exclusion of certain individuals and entities from participation in Medicare and State healthcare programs

Categories:

- Bills and statutes

U.S. Code: 42 U.S.C. § 1320a-7

Year enacted: 1981

Major amendments: 1981, 1984, 1986, 1987, 1988, 1989, 1990, 1991, 1994, 1997, 2003, 2010, 2019

Enforcement agencies: U.S. Department of Health & Human Services (HHS) Office of Inspector General (OIG)

Links to full text of law:

- https://www.govinfo.gov/content/pkg/USCODE-2021-title42/pdf/USCODE-2021-title42-chap7-subchapXI-partA-sec1320a-7.pdf

Applies to: Any individual or entity who is convicted of a program-related crime, a conviction relating to patient abuse, a felony conviction relating to health care fraud, and a felony conviction relating to controlled substance.

The US Department of Health and Human Services (HHS) Office of Inspector General (HHS-OIG, hereafter OIG) has the authority to exclude individuals and entities from federally funded healthcare programs for an array of reasons, including criminal and civil liability for Medicare or Medicaid fraud. The Secretary of HHS has designated the OIG as the excluding authority under regulations contained in Chapter V of Title 42 of the Code of Federal Regulations. An excluded individual or entity shall receive no payment from federal healthcare programs for individual salary and benefits or for any items or services they furnish, order, or prescribe. This includes those entities that provide health benefits funded directly or indirectly by the United States (other than the Federal Employees Health Benefits Plan).[2][3]

OIG maintains a list of all currently excluded individuals and entities called the List of Excluded

Individuals/Entities (LEIE) (i.e. sanctions list). Information about the LEIE may be found on the OIG's exclusions page[4]. Anyone who hires or contracts with an individual or entity on the LEIE may be subject to civil monetary penalties (CMP). Federal laws generally prohibit providers from billing for services ordered or performed by persons or entities that have been excluded from participating in Medicare, Medicaid, or other federal healthcare programs. Violations may result in repayment of amounts improperly received and significant penalties. To avoid overpayments and penalties, providers should check the OIG's sanctions list before hiring, contracting with, or granting privileges to employees, contractors, or practitioners, and should periodically recheck the sanctions list.

Federal statutes such as the CMP Law authorizes OIG to exclude individuals and entities from participating in federal healthcare programs if they have been convicted of healthcare fraud or engaged in certain other criminal or civil misconduct (See, e.g., 42 USC §§ 1320a-7 and 1320c-5). Federal healthcare programs include state healthcare programs, such as state Medicaid programs, the Maternal and Child Health Services Block Grant, block grants to states for social services and the children's health insurance program.[5]

Federal Exclusions

Mandatory Exclusions

Federal regulations provide that exclusion from future participation in federal healthcare programs is *mandatory* upon conviction of (1) a program-related crime, (2) a criminal offense related to neglect or abuse of patients, (3) a felony conviction relating to healthcare fraud, or (4) a felony conviction relating to a controlled substances offense.[6] For purposes of this exclusion, the term "federal healthcare program" includes programs funded in *whole or in part* by the United States.[7] For a first time offender, in most instances the minimum period of exclusion is five years.[8] For an individual convicted of an offense occurring after August 5, 1997, who has a prior conviction for which exclusion is required by subsection (a), the minimum term of exclusion is 10 years.[9] If the individual has two prior convictions, the exclusion is permanent.[10]

For purposes of imposition of an exclusion, a conviction occurs when a judgment of conviction is entered regardless of whether an appeal is pending, when there has been a finding of guilt in court, when a plea of guilty or *nolo contendere* has been accepted by the court, or when an individual enters into participation in a first offender, deferred adjudication, or other arrangement where judgment of conviction has been withheld.[11] There would not be a basis for exclusion if there was a determination of non-prosecution and dismissal of the case. The conviction implicates the exclusion provisions regardless of whether it occurred in federal, state, or local court.[12]

Significantly, federal law also specifies exclusion from the state administered Medicaid programs in many instances. Mandatory Medicaid exclusion is called for whenever a provider has been excluded from Medicare.[13] Additionally, in the case of providers operating in multiple states, exclusion of the provider by any one state's Medicaid program requires that all other state Medicaid programs exclude the provider as well.[14] Mandatory exclusion from Medicaid is also required if the provider has failed to unilaterally refund any program overpayment within 60 days or under certain circumstances is affiliated with an excluded person.[15]

Permissive Exclusion

Title 42, section 1320a-7(b) of the United States Code provides a list of transgressions that authorize the Secretary of Health and Human Services[16] to exclude the transgressing individuals from participating in a

federal healthcare program. This is a discretionary (i.e. not mandatory) decision for the OIG and is commonly referred to as permissive exclusions and are authorized for the following persons or entities:

1. An individual convicted of a misdemeanor healthcare fraud offense;[17]
2. An individual convicted of a criminal offense related to fraud, theft, embezzlement, breach of fiduciary duty, or other financial misconduct with respect to participation in a program (other than a healthcare program) operated by or financed in whole or in part by a federal, state, or local government;[18]
3. An individual convicted of obstruction of justice in relation to an underlying offense, the conviction for which would cause mandatory exclusion;[19][20]
4. An individual excluded from a sister federal healthcare program or a state healthcare program;[21]
5. An individual who submits claims which are for services substantially in excess of the needs of patients or which fail to meet professionally recognized standards of healthcare;[22]
6. Any individual or entity that the Secretary determines has committed fraud, kickbacks, or other prohibited activity described in 42 U.S.C. § 1320a-7a, 42 U.S.C. § 1320a-7(b)(7).

While sub-section (b) contains other permissive exclusions, the basis mentioned above are the most likely to be encountered. The indicated term of exclusion for persons excluded under subsections (b)(1), (b)(2), or (b)(6) is three years unless the Secretary determines that a shorter or longer sanction is appropriate.[23] In many cases, the OIG does not seek a permissive exclusion in return for a healthcare organization's agreement to enter into a corporate integrity agreement (CIA).

Of particular import is the basis for exclusion in number 6 above. Section 1320a-7b and the conduct it proscribes may be the subject of criminal proceedings. However, § 1320a-7a provides civil monetary penalties for a range of conduct including kickbacks and improper filing of claims. Consequently, the Secretary can impose a period of exclusion absent a criminal conviction and will frequently make it part of any settlement of a civil False Claims Act (FCA) case brought by the Department of Justice.

Also of particular relevance to compliance professionals is the permissive exclusion of entities controlled by a sanctioned individual.[24] That section provides that the Secretary *may* exclude:

Any entity with respect to which the Secretary determines that a person —

> (A)(i) who has a direct or indirect ownership or control interest of 5 percent or more in the entity or with an ownership or control interest (as defined in Section 1320a-3(a)(3) of this title) in that entity;
>
> who is an officer, director, agent, or managing employee (as defined in Section 1320a-5(b) of this title) of that entity; or
>
> (iii) who was described in clause (i) but is no longer so described because of a transfer of ownership or control interest, in anticipation of (or following) a conviction, assessment, or exclusion described in subparagraph (B) against the person, to an immediate family member (as defined in subsection (j)(1) of this section) or a member of the household of the person (as defined in subsection (j)

> (2) of this section) who continues to maintain an interest described in such clause-

is a person –

> (B)(i) who has been convicted of any offense described in subsection (a) of this section or in paragraph (1), (2), or (3) of this subsection;
>
> (ii) against whom a civil monetary penalty has been assessed under sections 1320a-7a or 1320a-8 of this title; or
>
> (iii) who has been excluded from participation under a program under subchapter XVIII of this chapter or under a State health care program.

It is worth highlighting that this section provides permissive exclusion when an individual transfers ownership of an entity to a family member in anticipation that the transferor will become subject to the exclusion.

The statute also contains a similar provision for permissive exclusion of individuals who control a convicted or excluded entity.[25] Such permissive exclusion is limited to (1) those individuals who have direct or indirect ownership or control interest in the entity and who knew or should have known of the action constituting the basis for conviction or exclusion, or (2) officers and managing employees of the sanctioned entity.

The scope of exclusion can also reach individuals who provide administrative or managerial services to federal health program participants. Excluded persons and entities are prohibited from furnishing administrative and management services that are payable by federal healthcare programs. According to OIG, an excluded individual may not serve in an executive leadership role (*e.g.*, CEO, CFO, general counsel, HR director, HIM director, office manager, etc.) at a provider that furnishes items or services payable by federal healthcare programs. Furthermore, the OIG takes the position that an excluded individual may not provide other types of administrative and management services (*e.g.*, HIM services, HR, billing, accounting, strategic planning, etc.), unless wholly unrelated to federal healthcare programs. (*Id.*) (OIG, *Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs* (8/13), hereafter "OIG Bulletin (8/13)).”

The statutory exclusions set forth in 42 U.S.C. § 1320a-7 are also set forth in the regulations pertaining to the Office of the Inspector General of the Department of Health and Human Services at 42 C.F.R. sections 1001.101 and 1001.102 (mandatory exclusion), and 42 C.F.R. sections 1001.201 to 1001.1701 (permissive exclusions). Section 1001.102 and each of the permissive exclusion sections set forth guidelines that the Inspector General should consider in determining the length of a particular exclusion.

OIG has the legal authority to impose CMPs on individuals and entities that arrange or contract (by employment or otherwise) with an individual or entity that the person knows or should know is excluded from participation in a federal healthcare program for the purpose of providing items and services for which payment may be made by a federal healthcare program.[26] OIG may impose penalties for each item or service furnished by the excluded individual or entity for which a claim was submitted to a federal healthcare program.

To avoid overpayment and CMP liability, entities participating in federal healthcare programs should check the sanctions list before employing or contracting with individuals or entities, and periodically check the sanctions list to determine the exclusion status of current employees and contractors. The LEIE is a tool that OIG has made available to providers and others to enable them to identify potential and current employees or contractors that are excluded by OIG. If an entity discovers that it has employed or contracted with an excluded individual or

entity, the entity should evaluate its overpayment and CMP liability. It is recommended that entities in this situation consider whether to submit a self-disclosure through the Health Care Fraud Self-Disclosure Protocol.[27] OIG updates the sanctions list monthly, so screening each month best minimizes potential overpayment and CMP liability.

Many state Medicaid programs now have their own exclusion authorities and maintain their own state exclusion lists. If an entity employs or contracts or otherwise engages with individuals or entities excluded from a state Medicaid program in which it participates, the entity may incur overpayment and/or CMP liability. OIG recommends that entities check employees, contractors, and other individuals or entities that provide items and services that may be paid for by the state Medicaid programs in which they participate against such state Medicaid program exclusion lists. For example, if an entity has a hospital in Illinois that participates on the Illinois and Iowa state Medicaid programs, OIG recommends that the entity screen all employees and contractors who provide items or services at the facility, or who provide support to the facility, against both Illinois and Iowa state Medicaid exclusion lists.

Procedures

Once the secretary makes a determination to impose an exclusion, they must provide notice of the exclusion to the provider.[28] The notice will contain instructions for responding to the notice and inform the provider that they have 60 days to request a hearing on the proposed exclusion.[29] The request for the hearing must contain a statement as to the specific findings of fact and conclusions of law to which the provider objects.[30] The hearing will be held by an administrative law judge. At the hearing, the provider has the rights to:

1. Be accompanied, represented, and advised by an attorney;
2. Participate in any conference held by the ALJ;
3. Conduct discovery of documents;
4. Agree to stipulations of fact or law which will be made part of the record;
5. Present evidence relevant to the issues at the hearing;
6. Present and cross-examine witnesses;
7. Present oral arguments at the hearing as permitted by the ALJ; and
8. Submit written briefs and proposed findings of fact and conclusions of law after the hearing.[31]

Procedural rules governing the hearings, including discovery rules, are contained in 42 C.F.R. sections 1005.7-1005-14. In the case of permissive exclusions under sections 1001.701 (Excessive claims or furnishing of unnecessary or substandard items and services), 1001.901 (False and improper claims), and 1001.951 (Fraud and kickbacks and other prohibited activities), the provider has the burden of going forward and of persuasion with respect to affirmative defenses, and the OIG bears the burden of proof on all other issues.[32] In all other cases, the ALJ allocates the burden of proof as the ALJ determines is appropriate.[33] The ALJ may, but need not, apply the Federal Rules of Evidence, 42 C.F.R. section 1005.17(b), but must exclude irrelevant or immaterial evidence.[34] The ALJ must issue a decision within 60 days of the time for the filing of post-trial briefs and may affirm, increase, or decrease the previously imposed exclusion.[35]

Any party may appeal the decision of the ALJ to the Departmental Appeals Board of the U.S. Department of Health and Human Services (DAB). A notice of appeal must be filed within 30 days, and the notice must be accompanied by a brief specifying exceptions to the initial decision and reasons supporting the exceptions.[36] The DAB may decline to review the case or may affirm, increase, reduce, reverse, or remand any penalty or exclusion.[37] The DAB reviews factual findings to determine whether substantial evidence in the record supports the finding and reviews legal conclusions for error.[38]

Final exclusion decisions may be appealed from the DAB to the United States District Court in the District where the appellant resides or has their principal place of business.[39] Final judgments in the District Court may be appealed in the normal course to a United States Court of Appeals. The procedural rules applicable to exclusion administrative appeals include presumptions which are favorable to the government, making it difficult to overturn exclusion actions upon appeal.

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. To participate in Medicare, Medicaid, and all other federal healthcare 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. five 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 healthcare license in the same state, (2) have obtained any healthcare license in a different state, or (3) do not possess a valid healthcare license of any kind in any state but have been excluded for a minimum period of three years.[40] Obtaining a provider number from a Medicare contractor, a state healthcare program, or a federal healthcare program does not reinstate an individual's or entity's eligibility to participate in those programs.[41] 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, the individual entity must 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 OIG.