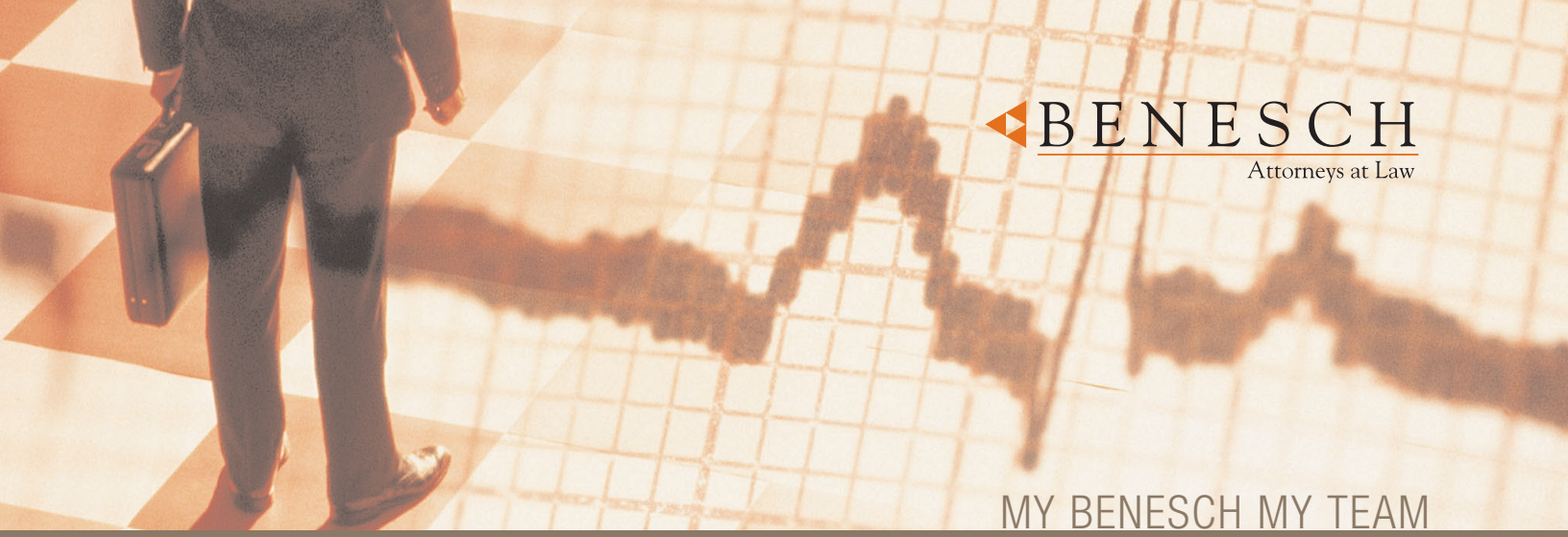

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ISSUE BRIEF

Benesch National Health Care Practice

INDIVIDUALS EXCLUDED FROM FEDERAL HEALTH CARE PROGRAMS OR FEDERAL CONTRACTING: PROTECTING YOUR ORGANIZATION

By: Ari J. Markenson, J.D., M.P.H.

The enforcement of penalties for employing or contracting with individuals or businesses that are excluded from Federal Health Care Programs or federal contracts seems to be on an upswing. While this is not a new issue, there definitely appears to be renewed interest at both the federal and state levels. It is also worth noting that there still are reports of significant violations of the rules occurring and so the renewed interest in enforcement is paying off at a time when governments need additional sources of revenue. In that respect the likelihood of enforcement activity on this issue subsiding soon is pretty low.

This issue brief discusses the relevant laws and regulations relating to excluded parties and the ways in which health care providers can implement systems to prevent exposure to excluded parties.

What is an Excluded Party?

Excluded parties in the health care context generally refer to persons or entities (i.e. businesses) who have either been excluded from participation in Federal Health Care Programs or excluded from participation in federal contracts.

The Secretary of the U.S. Department of Health and Human Services ("DHHS') is given the authority by Congress, pursuant to 42 U.S.C. §1320a-7, to exclude individuals and entities from participation in Federal Health Care Programs. The authority to exclude has been delegated to the Office of the Inspector General of DHHS (the "OIG").

Individuals who are excluded from Federal Health Care Programs cannot effectively participate in the provision of health care to individuals with coverage under a Federal Health Care Program. Federal Health Care Programs include Medicare, Medicaid and any other health care program funded directly or indirectly by the Federal Government. Exclusion in its most basic sense means that no payment can be made by any Federal Health Care Program for any items or services furnished, ordered, or prescribed by an individual or entity that has been excluded. The OIG maintains a searchable list of excluded individuals and entities (the "LEIE") on its website.

In addition to OIG exclusions, The U.S. General Services Administration ("GSA") maintains a comprehensive list of individuals and entities that have been excluded from participation in Federal contracts. The exclusions listed on the GSA's excluded parties list system ("EPLS") are a compilation of lists and information of persons and entities that have been excluded by federal government agencies and therefore prohibited from receiving federal contracts, federally approved subcontracts, and from certain types of federal financial and nonfinancial assistance and benefits. The exclusion actions that lead to a person or entity being listed in the EPLS may come from specific action taken under the Federal Acquisition Regulation ("FAR"), under specific federal agency regulations or under the Federal

Government-wide Nonprocurement Suspension and Debarment Common Rule, 68 FR 66533.

What are the penalties for employing or contracting with an Excluded Party?

FEDERAL HEALTH CARE PROGRAM EXCLUSIONS

Medicare and Medicaid providers found to be contracting with excluded parties can be subject to significant penalties and recovery of funds by the federal or state governments. There is a broad-based payment ban found in 42 C.F.R. §1001.1901(b) that provides:

"[N]o payment will be made by Medicare, Medicaid or any of the other Federal health care programs for any item or service furnished...by an excluded individual or entity, or at the medical direction or on the prescription of a physician or other authorized individual who is excluded when the person furnishing such item or service knew or had reason to know of the exclusion..."

The payment ban extends to:

- all methods of Federal Health Care Program reimbursement, whether payment results from itemized claims, cost reports, fee schedules, or a prospective payment system;
- payment for administrative and management services not directly related to patient care, but that are a necessary component of providing items and services to Federal Health Care Program recipients, when those payments are reported on a cost report or are otherwise payable by a Federal Health Care Program;
- any items and services furnished at the medical direction or prescription of an excluded physician;
- payment to cover an excluded individual's salary, expenses or fringe benefits, regardless of whether they provide direct patient care, when those payments are reported on a cost report or are otherwise payable by a Federal Health Care Program; and
- payment even when the Federal Health Care Program payment itself is made to another provider, practitioner or supplier that is not excluded.

In addition to the payment ban, the Federal Civil Money Penalties Law, 42 U.S.C. §1320a-7a (the "CMP Law") includes several provisions relating to doing business with excluded individuals and entities that provide for significant penalties.

42 U.S.C. §1320a-7a(a)(1)(D) provides that "[a]ny person (including an organization, agency, or other entity, but excluding a beneficiary...) that—(1) knowingly presents or causes to be presented to [a Federal Health Care Program] ... a claim ...that the Secretary determines- ... (D) is for a medical or other item or service furnished during a period in which the person was excluded from [a Federal Health Care Program]... shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than $10,000 for each item or service ... In addition, such a person shall be subject to an assessment of not more than 3 times the amount claimed for each such item or service in lieu of damages sustained by the United States or a State agency because of such claim... In addition the Secretary may make a determination in the same proceeding to exclude the person from participation in the Federal health care programs...and to direct the appropriate State agency to exclude the person from participation in any State health care program."

42 U.S.C. §1320a-7a(a)(4) provides that "[a]ny person (including an organization, agency, or other entity, but excluding a beneficiary ...that- (4) in the case of a person who is not an organization, agency, or other entity, is excluded from participating in a [a Federal Health Care Program] ... and who, at the time of a violation of this subsection- (A) retains a direct or indirect ownership or control interest in an entity that is participating in [a Federal Health Care Program] and who knows or should know of the action constituting the basis for the exclusion; or (B) is an officer or managing employee ...of such an entity... shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of ...$10,000 for each day the prohibited relationship occurs...In addition, such a person shall be subject to an assessment of not more than 3 times the amount claimed for each such item or service in lieu of damages sustained by the United States or a State agency because of such claim... In addition the Secretary may make a determination in the same proceeding to exclude the person from participation in the Federal health care programs ...and to direct the appropriate State agency to exclude the person from participation in any State health care program."

42 U.S.C. §1320a-7a(a)(6) provides that "[a]ny person (including an organization, agency, or other entity, but excluding a beneficiary ...that- (6) arranges or contracts (by employment or otherwise) with an individual or entity that the person knows or should know is excluded from participation in a Federal health care program ...for

the provision of items or services for which payment may be made under such a program... shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than $10,000 for each item or service ... In addition, such a person shall be subject to an assessment of not more than 3 times the amount claimed for each such item or service in lieu of damages sustained by the United States or a State agency because of such claim... In addition the Secretary may make a determination in the same proceeding to exclude the person from participation in the Federal health care programs...and to direct the appropriate State agency to exclude the person from participation in any State health care program."

Each of these provisions makes clear that doing business with excluded individuals or entities can result in significant penalties. The individual or entity submitting claims can be liable for $10,000 CMPs per item or service claimed or "caused to be" claimed plus treble damages and subject to possible exclusion.

Each of the activities listed in the CMP Law can also be the subject of administrative sanctions by the OIG pursuant to its regulatory authority in 42 C.F.R. §1003.102.

Depending upon the circumstances there is also the possibility of liability under the Federal False Claims Act, 31 U.S.C. §3729, if the activity that led to the submission of claims for items or services provided by excluded individuals meets the elements of the statute. Additionally, whistleblowers who are aware of the employment or association with excluded individuals or entities can attempt to bring Qui Tam actions under the Federal False Claims Act.

FEDERAL ACQUISITION REGULATION— GOVERNMENT-WIDE DEBARMENT OR SUSPENSION

Section §2455 of Federal Acquisition Streamlining Act of 1994 (31 U.S.C. §6101 Note) provides that "No [Federal] agency shall allow a party to participate in any procurement or nonprocurement activity if any agency has debarred, suspended, or otherwise excluded (to the extent specified in the exclusion agreement) that party from participation in a procurement or nonprocurement activity."

Additionally, 48 C.F.R §9.405 provides that—

"(a) Contractors debarred, suspended, or proposed for debarment are excluded from receiving contracts, and agencies shall not solicit offers from, award contracts to, or consent to subcontracts with these contractors, ...[further] Contractors debarred, suspended, or proposed for debarment are also excluded from conducting business with the Government as agents or representatives of other contractors.

(b) Contractors included in the EPLS as having been declared ineligible on the basis of statutory or other regulatory procedures are excluded from receiving contracts, and if applicable, subcontracts, under the conditions and for the period set forth in the statute or regulation. Agencies shall not solicit offers from, award contracts to, or consent to subcontracts with these contractors under those conditions and for that period."

45 C.F.R §76.110(d) provides that "Any exclusion from [Federal Health Care Programs]... on or after August 25, 1995 shall be recognized by and effective, not only for all HHS programs, but also for all other Executive Branch procurement and nonprocurement activities." In that respect, an exclusion from Federal Health Care Programs becomes an exclusion from federal procurement programs and will cause a listing on the EPLS.

For Medicare providers, the Centers for Medicare and Medicaid Services ("CMS") generally has the authority to deny or revoke Medicare enrollment for individuals or entities who either are, or are doing business with, individuals or entities that are listed on the EPLS as debarred, suspended, or otherwise excluded from federal programs.

42 C.F.R. §424.530 provides that CMS may deny Medicare enrollment where "[a] provider, supplier, an owner, managing employee, an authorized or delegated official, medical director, supervising physician, or other health care personnel furnishing Medicare reimbursable services who is required to be reported on the enrollment application, in accordance with section 1862(e)(1) of the Act, is-[e]xcluded from the Medicare, Medicaid and any other Federal health care programs, ...[or] [d]ebarred, suspended, or otherwise excluded from participating in any other Federal procurement or nonprocurement activity ..."

Additionally, CMS requires Medicare providers and suppliers to certify compliance with certain standards pursuant to 42 C.F.R. §424.516. One of those standards, in 42 C.F.R. §424.516(a)(3) is that the provider or supplier is not "...employing or contracting with individuals or entities that [are] ...[e]xcluded from participation in any Federal health care programs ... [or] [d]ebarred by the General Services Administration (GSA) from any other Executive Branch procurement or nonprocurement programs or activities..." Pursuant to 42 C.F.R. §424.535(a)(1), CMS may revoke the billing privileges of any Medicare provider or supplier and any corresponding provider agreement or supplier agreement, where the provider or supplier is found to be out of compliance with certain requirements, including the certification requirements in 42 C.F.R. §424.516(a)(3).

CMS may also revoke the billing privileges of any Medicare provider or supplier and any corresponding provider agreement or supplier agreement, where the provider or supplier, pursuant to 42 C.F.R. §424.535(a)(2), where CMS determines that "[t]he provider or supplier, or any owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider or supplier is-(i) [e]xcluded from the Medicare, Medicaid, and any other Federal health care program... or (ii) ...debarred, suspended, or otherwise excluded from participating in any other Federal procurement or nonprocurement program or activity in accordance with the FASA implementing regulations and the Department of Health and Human Services nonprocurement common rule at 45 CFR part 76."

Overall, when dealing with an individual or entity that is listed on the EPLS as debarred, suspended, or otherwise excluded from federal programs, CMS has the authority to deny or revoke the Medicare number of the provider or supplier. On average most providers and suppliers receive a significant portion of their revenue from Medicare and revocation or denial can be a significant penalty. Furthermore, Section §6501 of the Patient Protection and Affordable Care Act (the "Health Reform Bill") requires state Medicaid programs to terminate any provider or supplier that has been terminated from the Medicare program. On a going forward basis, providers or suppliers terminated from Medicare will face termination from Medicaid as well.

How can you protect your organization?

Ensuring that your organization does not inappropriately employ or contract with individuals or entities who have been excluded from participation in Federal Health Care Programs or excluded, suspended or debarred from participation in federal contracts can be done with the implementation of two fairly simple processes. First, your organization can require the disclosure of any exclusion, suspension or debarment as part of the process of entering into new relationships with employees and contractors. Second, your organization can routinely check employees and contractors against the publically available data on exclusions, suspensions and debarments.

PREVENTION—NEW RELATIONSHIPS

Your organization should implement a policy that asks new employees or contractors, prior to associating with them, to affirmatively disclose whether or not they currently are, or ever have been, excluded, suspended or debarred from Federal Health Care Programs or federal contracts as well as whether they are currently subject to any type of judicial or administrative process that might lead to a possible exclusion, suspension or debarment. Additionally, that policy or another policy should also require your organization to confirm that the individual or entity does not appear on either of the applicable federal databases as well as any state database that may exist for Medicaid.

Exclusions from Federal Health Care Programs can be reviewed be searching the electronic searchable database of the OIG LEIE that is available at:

http://oig.hhs.gov/fraud/exclusions/exclusions_list.asp

Exclusion, suspensions, and debarments from federal contracts can be reviewed by searching the electronic searchable database of the GSA EPLS that is available at:

https://www.epls.gov/

To the extent your state has its own electronic searchable database of Medicaid exclusions, the policy should also cover a review of that database.

The types of individuals and entities that should regularly be subject to this type of pre-relationship screening include, but are not limited to: new employees, independent contractors, vendors, and referral sources.

ONGOING REVIEW

Your organization's compliance professionals should be responsible for ensuring that on an ongoing basis, all of the same types of individuals and entities that are screened on a pre-relationship basis are also screened periodically to ensure that they have not subsequently been subject to a exclusion, suspension or debarment. This periodic screening can be done on a regular monthly or quarterly schedule.

In order to determine what schedule makes sense, your organization has to determine the possible risks involved. For example, if your employees, on an individual basis, regularly generate significant Medicare and Medicaid revenue, the risk of finding out several months into an issue can outweigh the human and financial cost of conducting monthly screenings.

Additionally, your organization should consider requiring an annual certification from employees and contractors that provides that they are not currently nor have they ever been, excluded, suspended or debarred from Federal Health Care Programs or federal contracts and they are not currently subject to any type of judicial or administrative process that might lead to a possible exclusion, suspension or debarment.

Taken together all of these actions can significantly protect your organization from the potential penalties and real implications of doing business with individuals or entities that are either excluded from participation in Federal Health Care Programs or excluded, suspended or debarred from participation in federal contracts.

Additional Information

For more information on exclusions from Federal Health Care Programs or exclusions, suspensions or debarment from federal contracts, please contact a member of Benesch's Health Care Department:

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