Special Advisory Bulletin

The Effect of Exclusion From Participation in Federal Health Care Programs

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A. Introduction

The Office of Inspector General (OIG) was established in the U.S. Department of Health and Human Services to identify and eliminate fraud, waste, and abuse in the Department's programs and to promote efficiency and economy in Departmental operations. The OIG carries out this mission through a nationwide program of audits, inspections, and investigations. In addition, the OIG has been given the authority to exclude from participation in Medicare, Medicaid and other Federal health care programs[(1)] individuals and entities who have engaged in fraud or abuse, and to impose civil money penalties (CMPs) for certain misconduct related to Federal health care programs (sections 1128 and 1128A of the Social Security Act (the Act)).

Recent statutory enactments have strengthened and expanded the OIG's authority to exclude individuals and entities from the Federal health care programs. These laws also expanded the OIG's authority to assess CMPs against individuals and entities that violate the law. With this expanded authority, the OIG believes that it is important to explain the effect of program exclusions under the current statutory and regulatory provisions.

The Health Insurance Portability and Accountability Act (HIPAA) of 1996, Public Law 104-191, authorized the OIG to provide guidance to the health care industry to prevent fraud and abuse, and to promote high levels of ethical and lawful conduct. To further these goals, the OIG issues Special Advisory Bulletins about industry practices or arrangements that potentially implicate the fraud and abuse authorities subject to enforcement by the OIG.

In order to assist all affected parties in understanding the breadth of the payment prohibitions that apply to items and services provided to Federal program beneficiaries,[(2)] this Special Advisory Bulletin provides guidance to individuals and entities that have been excluded from Federal health care programs, as well as to those who might employ or contract with an excluded individual or entity to provide items or services reimbursed by a Federal health care program.

B. Statutory Background

In 1977, in the Medicare-Medicaid Anti-Fraud and Abuse Amendments, Public Law 95-142, Congress first mandated the exclusion of physicians and other practitioners convicted of program-related crimes from participation in Medicare and Medicaid (now codified at section 1128 of the Act). This was followed in 1981 with Congressional enactment of the Civil Monetary Penalties Law (CMPL), Public Law 97-35, to further address health care fraud and abuse (section 1128A of the Act). The CMPL authorizes the Department and the OIG to impose CMPs, assessments and program exclusions against

individuals and entities who submit false or fraudulent, or otherwise improper claims for Medicare or Medicaid payment. "Improper claims" include claims submitted by an excluded individual or entity for items or services furnished during a period of program exclusion.

To enhance the OIG's ability to protect the Medicare and Medicaid programs and beneficiaries, the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100-93, expanded and revised the OIG's administrative sanction authorities by, among other things, establishing certain mandatory and discretionary exclusions for various types of misconduct.

The enactment of HIPAA in 1996 and the Balanced Budget Act (BBA) of 1997, Public Law 105-33, further expanded the OIG's sanction authorities. These statutes extended the application and scope of the current CMP and exclusion authorities beyond programs funded by the Department to all "Federal health care programs." BBA also authorized a new CMP authority to be imposed against health care providers or entities that employ or enter into contracts with excluded individuals for the provision of services or items to Federal program beneficiaries.

In the discussion that follows, it should be understood that the prohibitions being described apply to items and services provided, directly or indirectly, to Federal program beneficiaries. The ability of an excluded individual or entity to render items and services to others is not affected by an OIG exclusion.

C. Exclusion from Federal Health Care Programs

The effect of an OIG exclusion from Federal health care programs is that no Federal health care program payment may be made for any items or services (1) furnished by an excluded individual or entity, or (2) directed or prescribed by an excluded physician (42 CFR 1001.1901). This payment ban applies to all methods of Federal program reimbursement, whether payment results from itemized claims, cost reports, fee schedules or a prospective payment system (PPS). Any items and services furnished by an excluded individual or entity are not reimbursable under Federal health care programs. In addition, any items and services furnished at the medical direction or prescription of an excluded physician are not reimbursable when the individual or entity furnishing the services either knows or should know of the exclusion. This prohibition applies even when the Federal payment itself is made to another provider, practitioner or supplier that is not excluded.

The prohibition against Federal program payment for items or services furnished by excluded individuals or entities also extends to 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 program beneficiaries. This prohibition continues to apply to an individual even if he or she changes from one health care profession to another while excluded.(3) In addition, no Federal program payment may be made to cover an excluded individual's salary, expenses or fringe benefits, regardless of whether they provide direct patient care.

Set forth below is a listing of some of the types of items or services that are reimbursed by Federal health care programs which, when provided by excluded parties, violate an OIG exclusion. These examples also demonstrate the kinds of items and services that excluded parties may be furnishing which will subject their employer or contractor to possible CMP liability.

- Services performed by excluded nurses, technicians or other excluded individuals who work for a hospital, nursing home, home health agency or physician practice, where such services are related to administrative duties, preparation of surgical trays or review of treatment plans if such services are reimbursed directly or indirectly (such as through a PPS or a bundled payment) by a Federal health care program, even if the individuals do not furnish direct care to Federal program

beneficiaries;

- Services performed by excluded pharmacists or other excluded individuals who input prescription information for pharmacy billing or who are involved in any way in filling prescriptions for drugs reimbursed, directly or indirectly, by any Federal health care program;

- Services performed by excluded ambulance drivers, dispatchers and other employees involved in providing transportation reimbursed by a Federal health care program, to hospital patients or nursing home residents;

- Services performed for program beneficiaries by excluded individuals who sell, deliver or refill orders for medical devices or equipment being reimbursed by a Federal health care program;

- Services performed by excluded social workers who are employed by health care entities to provide services to Federal program beneficiaries, and whose services are reimbursed, directly or indirectly, by a Federal health care program;

- Administrative services, including the processing of claims for payment, performed for a Medicare intermediary or carrier, or a Medicaid fiscal agent, by an excluded individual;

- Services performed by an excluded administrator, billing agent, accountant, claims processor or utilization reviewer that are related to and reimbursed, directly or indirectly, by a Federal health care program;

- Items or services provided to a program beneficiary by an excluded individual who works for an entity that has a contractual agreement with, and is paid by, a Federal health care program; and

- Items or equipment sold by an excluded manufacturer or supplier, used in the care or treatment of beneficiaries and reimbursed, directly or indirectly, by a Federal health care program.

D. Violation of an OIG Exclusion By an Excluded Individual or Entity

An excluded party is in violation of its exclusion if it furnishes to Federal program beneficiaries items or services for which Federal health care program payment is sought. An excluded individual or entity that submits a claim for reimbursement to a Federal health care program, or causes such a claim to be submitted, may be subject to a CMP of $10,000 for each item or service furnished during the period that the person or entity was excluded (section 1128A(a)(1)(D) of the Act). The individual or entity may also be subject to treble damages for the amount claimed for each item or service. In addition, since reinstatement into the programs is not automatic, the excluded individual may jeopardize future reinstatement into Federal health care programs (42 CFR 1001.3002).

E. Employing an Excluded Individual or Entity

As indicated above, BBA authorizes the imposition of CMPs against health care providers and entities that employ or enter into contracts with excluded individuals or entities to provide items or services to Federal program beneficiaries (section 1128A(a)(6) of the Act; 42 CFR 1003.102(a)(2)). This authority parallels the CMP for health maintenance organizations that employ or contract with excluded individuals (section 1857(g)(1)(G) of the Act). Under the CMP authority, providers such as hospitals, nursing homes, hospices and group medical practices may face CMP exposure if they submit claims to a Federal health care program for health care items or services provided, directly or indirectly, by

excluded individuals or entities.

Thus, a provider or entity that receives Federal health care funding may only employ an excluded individual in limited situations. Those situations would include instances where the provider is both able to pay the individual exclusively with private funds or from other non-federal funding sources, and where the services furnished by the excluded individual relate solely to non-federal program patients.

In many instances, the practical effect of an OIG exclusion is to preclude employment of an excluded individual in any capacity by a health care provider that receives reimbursement, indirectly or directly, from any Federal health care program.

F. CMP Liability for Employing or Contracting with an Excluded Individual or Entity

If a health care provider arranges or contracts (by employment or otherwise) with an individual or entity who is excluded by the OIG from program participation for the provision of items or services reimbursable under such a Federal program, the provider may be subject to CMP liability if they render services reimbursed, directly or indirectly, by such a program. CMPs of up to $10,000 for each item or service furnished by the excluded individual or entity and listed on a claim submitted for Federal program reimbursement, as well as an assessment of up to three times the amount claimed and program exclusion may be imposed. For liability to be imposed, the statute requires that the provider submitting the claims for health care items or services furnished by an excluded individual or entity "knows or should know" that the person was excluded from participation in the Federal health care programs (section 1128A(a)(6) of the Act; 42 CFR 1003.102(a)(2)). Providers and contracting entities have an affirmative duty to check the program exclusion status of individuals and entities prior to entering into employment or contractual relationships, or run the risk of CMP liability if they fail to do so.

G. How to Determine If an Individual or Entity is Excluded

In order to avoid potential CMP liability, the OIG urges health care providers and entities to check the OIG List of Excluded Individuals/Entities on the OIG web site (www.hhs.gov/oig) prior to hiring or contracting with individuals or entities. In addition, if they have not already done so, health care providers should periodically check the OIG web site for determining the participation/exclusion status of current employees and contractors. The web site contains OIG program exclusion information and is updated in both on-line searchable and downloadable formats. This information is updated on a regular basis. The OIG web site sorts the exclusion of individuals and entities by: (1) the legal basis for the exclusion, (2) the types of individuals and entities that have been excluded, and (3) the State where the excluded individual resided at the time they were excluded or the State where the entity was doing business. In addition, the entire exclusion file may be downloaded for persons who wish to set up their own database. Monthly updates are posted to the downloadable information on the web site.

H. Conclusion

In accordance with the expanded sanction authority provided in HIPAA and BBA, and with limited exceptions[(4)], an exclusion from Federal health care programs effectively precludes an excluded individual or entity from being employed by, or under contract with, any practitioner, provider or supplier to provide any items and services reimbursed by a Federal health care program. This broad prohibition applies whether the Federal reimbursement is based on itemized claims, cost reports, fee schedules or PPS. Furthermore, it should be recognized that an exclusion remains in effect until the individual or entity has been reinstated to participate in Federal health care programs in accordance with the procedures set forth at 42 CFR 1001.3001 through 1001.3005. Reinstatement does not occur automatically at the end of a term of exclusion, but rather, an excluded party must apply for

reinstatement.

If you are an excluded individual or entity, or are considering hiring or contracting with an excluded individual or entity, and question whether or not the employment arrangement may violate the law, the OIG Advisory Opinion process is available to offer formal binding guidance on whether an employment or contractual arrangement may be in violation of the OIG's exclusion and CMP authorities. The process and procedure for submitting an advisory opinion request can be found at 42 CFR 1008, or on the OIG web site at www.hhs.gov/oig.

1. A Federal health care program is defined as any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government or a State health care program (with the exception of the Federal Employees Health Benefits Program) (section 1128B(f) of the Act). The most significant Federal health care programs are Medicare, Medicaid, Tricare and the Veterans programs.

2. A Federal program beneficiary is an individual that receives health care benefits that are funded, in whole or in part, by a Federal health care program.

3. For example, the prohibition against Federal program payment for items and services would continue to apply in the situation where an excluded pharmacist completes his or her medical degree and becomes a licensed physician.

4. In certain instances, a State health care program may request a waiver of an exclusion if an individual or entity is the sole community physician or the sole source of essential specialized services in a community (42 CFR 1001.1801(b)).