The Kiss of Death: OIG’s Exclusion Authority

By Scott McBride and Summer D. Swallow

The federal government’s latest actions to strengthen its permissive exclusion authority further evidence its recent focus toward individual accountability in its fraud and abuse enforcement activities. One of the Department of Health and Human Services Office of Inspector General’s most powerful measures in its fight against fraud and abuse is its ability to exclude companies or individuals from participation in federal health care programs.

The OIG’s exclusion authority yields the agency significant leverage in negotiations with alleged offenders, being that exclusion for many health care providers can effectively be a death sentence as Medicare and Medicaid are chief revenue sources for many providers. Although the OIG has not aggressively exercised its permissive exclusion authority, it recently indicated through new guidance and legislative initiative that it intends to make more frequent use of such authority.

No payment will be made by Medicare, Medicaid or 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. Additionally, a person or entity may not employ or contract with excluded individuals or entities to provide items or services, payable in whole or in part, directly or indirectly, under Medicare, Medicaid or other federal health care programs. According to the OIG, the prohibition applies “even if the excluded individual or entity providing the Federally payable items or services is paid with non-Federal funds, is paid by an unrelated third party, or provides items or services on an unpaid basis.”

In fiscal year 2009, the federal government won or negotiated approximately $1.63 billion in judgments and settlements in health care fraud cases and proceedings. During that same time period, the OIG excluded

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1 42 U.S.C.A. § 1320a-7
2 42 U.S.C.A. §§ 1395y(e), 1396a(a)(39); 42 C.F.R. § 1001.1901; The exclusion does not include payment for certain emergency items or services not provided in a hospital emergency room that are furnished by, or at the medical direction of, an excluded individual or entity.
4 The Dep’t of Health & Human Services and The Dep’t of Justice Health Care Fraud & Abuse Control Program Annual

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2,556 individuals and entities from participation in federal health care programs. This measure breaks down to an average of nearly seven exclusions per day. Among these were exclusions based on criminal convictions for crimes related to Medicare and Medicaid (780) or to other health care programs (277), for patient abuse or neglect (239) or as a result of licensure revocations (885).5

A Brief Background on Exclusions

The broadening power and authority of the federal government to exclude companies and individuals from participation in Medicare, Medicaid and other federal health care programs has evolved over time. In 1977, following congressional hearings that concluded existing penalties were not sufficient to deter Medicare and Medicaid fraud and abuse, the Medicare/Medicaid Fraud and Abuse Amendments of 1977 elevated fraud and abuse violations to felony status and mandated the exclusion of physicians and other practitioners convicted of program-related crimes from the Medicare and Medicaid programs.7 The passage of the Civil Monetary Penalties Law in 1981, granted to HHS the authority to impose civil monetary penalties (CMPs) and assessments on, and exclusion of, health care providers who file Medicare/Medicaid claims for service that they knew or had reason to know were not provided as claimed.8 The Medicare and Medicaid Patient and Program Protection Act of 1987 provides the OIG with administrative sanction authority and establishes certain mandatory and discretionary exclusions for various types of misconduct.9

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) expanded the already existing Medicare and Medicaid exclusions. The exclusion provisions of HIPAA included (1) broadening the OIG’s mandatory exclusion authority; (2) establishing minimum exclusion periods for certain discretionary exclusions; and (3) establishing a discretionary exclusion authority applicable to owners, officers and managers of sanctioned entities.10 The Balanced Budget Act further modified the OIG’s exclusion authority by instituting certain mandatory permanent exclusions and lengthening exclusionary sentences for repeat offenders.11 These exclusions also were made applicable to any entities owned or controlled by the family or household members of the excluded individuals.

In 1998, the OIG issued a final rule that implements the exclusion authorities set forth in HIPAA.12 The final rule established new minimum periods of exclusion, set

Strengthening The OIG’s Permissive Exclusion Authority

Exclusions are mandatory and not subject to OIG discretion when an individual or entity has been convicted of certain enumerated crimes including (1) Medicare or Medicaid fraud; (2) patient abuse or neglect; (3) felonies for other health care fraud; and (4) felonies for illegal manufacture, distribution, prescription or dispensing of controlled substances.16 Additionally, the OIG has permissive exclusion authority under 42 U.S.C. § 1320a-7(b) for, among other things, (1) lesser convictions, including misdemeanors for other health care fraud (other than Medicare or Medicaid) or for illegal manufacturing, distributing, prescribing or dispensing

out further mitigating factors to affect the length of exclusions and broadened the OIG’s exclusion authority to extend to indirect providers. In 1999, the OIG released a Special Advisory Bulletin entitled “Effect of Exclusion from Participation in Federal Health Care Programs” which lists examples of items and services that, when provided by an excluded individual or entity, may violate an OIG exclusion and subject a health care organization to sanctions.13 The OIG currently is soliciting public comments regarding potential updates to this special advisory bulletin on the effects of exclusions from federal health care programs.14

Under the Patient Protection and Affordable Care Act (PPACA), Congress established new grounds for permissive exclusion from federal health care programs, including for an individual or entity convicted of obstructing an audit related to a criminal offense relating to fraud.

Effective March 23, 2010, PPACA granted the OIG the authority to exclude any person or entity that makes false statements or misrepresents a material fact on an application, agreement, bid or contract to participate or enroll as a provider or supplier for federal health care programs.17 To enhance Medicaid integrity, PPACA requires states to terminate individuals or entities from their Medicaid programs if the individual or entity has been terminated from Medicare or from the Medicaid program of another state.18 However, the more expansive provisions provided for in Section 6502 of PPACA, which require, among other things, that State Medicaid agencies exclude individuals or entities from participating in Medicaid if the entity or individual owns, controls, or manages an entity that is affiliated with an individual or entity that has been suspended, excluded, or terminated from Medicaid participation, have been repealed by the recently enacted Medicare and Medicaid Extenders Act of 2010.19
of controlled substances; (2) suspension or revocation of a license to provide health care for reasons bearing on professional competence, professional performance or financial integrity; (3) provision of unnecessary or substandard services; (4) submission of false or fraudulent claims to a federal health care program; or (5) engaging in unlawful kickback arrangements.

Recent signals from the OIG indicate that the government intends to hold individuals in a position to influence a corporation found to have violated the law personally responsible for such corporation’s wrongdoing. The OIG recently issued guidance related to its permissive exclusion authority under Section 1128(b)(15) of the Social Security Act. Section 1128(b)(15) grants the Secretary of HHS, as delegated to the OIG, permissive exclusion authority over owners, officers or managing employees of a sanctioned entity. Specifically, the OIG may exclude owners if they had a direct or indirect ownership interest in a sanctioned entity and knew or should have known of the action that led to the sanction. Additionally, officers and managing employees of sanctioned entities are held to a higher standard and can be excluded even in the absence of evidence demonstrating knowledge of the underlying misconduct. Thus, the OIG could exclude officers or managing employees of a sanctioned entity based on their employment status alone. The term “managing employee” means, with respect to an entity, an individual, including a general manager, business manager, administrator, and director, who exercises operational or managerial control over the entity, or who directly or indirectly conducts the day-to-day operations of the entity.

Although the OIG historically has not exercised its permissive exclusion under Section 1128(b)(15), the recently issued guidance can be viewed as the government’s pronouncement of its intention to do so. The guidance identifies factors that the OIG will consider in determining whether to exercise its discretionary authority to exclude owners, officers and managing employees. With respect to owners, the OIG notes that if there is evidence that supports that the owner knew or should have known of the conduct, the OIG will “operate with a presumption in favor of exclusion.” The presumption can be overcome if the OIG finds that undiscovered “significant factors weigh against exclusion.”

With respect to officers and managing employees, the OIG asserts that since the statute includes no knowledge element, it can exclude every officer and managing employee of a sanctioned entity. However, the OIG says it does not intend to pursue such extreme measures. Rather, the OIG notes that if an officer or managing employee knew or should have known of the conduct, the OIG will “operate with a presumption in favor of exclusion.” As above, the presumption can be overcome if the OIG finds that “significant factors weigh against exclusion.”

The OIG guidance includes a series of questions that will be considered in determining whether the pre-

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19 See October 20, 2010 speech by Assistant Attorney General Tony West to the Pharmaceutical Regulatory and Compliance Congress in Washington, D.C, pointing to cases “that underscore our renewed focus on individual wrongdoers because where the facts and law allow, the civil division will pursue the individuals responsible for illegal conduct just as vigorously as we will companies.”


21 42 U.S.C. 1320a-7(b)(15).

22 42 U.S.C. § 1320a-7a.
sumption in favor of exclusion can be overcome. The questions relate to various factors, including the circumstances of the misconduct, the seriousness of the offense, the individual's role in the sanctioned entity, the individual's actions in response to the misconduct and information about the entity.

For example, the OIG will consider the following factors, among others: (1) whether beneficiaries were harmed; (2) the extent of any financial harm to federal health care programs; (3) whether the misconduct is an isolated incident or represents a pattern of wrongdoing; (4) If the entity previously had had any similar problems with the government; (5) the individual's role and responsibility in the entity including such person's position and relationship to the underlying misconduct; and (6) the size of the entity and its corporate structure.

Individual Accountability

The OIG recently has pursued exclusion for a number of corporate officers of sanctioned entities. In a recent OIG Semiannual Report to Congress, the OIG highlighted an administrative ruling affirming OIG's determination to exclude former Purdue Frederick executives from participation in federal health care programs for a period of 15 years.26 The exclusions were based on the executives' convictions for their failure in their roles as responsible corporate officers of Purdue Frederick to "prevent or correct" the misbranding of OxyContin. The Administrative Law Judge found that the executives' conduct "endangered the health and safety of program beneficiaries and others" and caused "astronomical" losses to government programs.

The OIG states that one purpose of the guidance is to "positively influence individuals' future behavior and compliance with Federal health care program requirements by holding individuals accountable for misconduct within entities in which they are in positions of responsibility." Further arming itself in its fight to hold individuals accountable, the OIG is, through legislative initiative, attempting to close off an existing loophole that allows executives to leave companies accused of fraud prior to conviction and thereby escape exclusion from federal health care programs.27 To that end, the proposed legislation would expand the OIG's power to exclude any individual who was an officer, managing employee or owner of the company (or affiliated entity) at the time the fraud occurred.27 The guidance asserts that the OIG's decision to exercise its discretionary authority under Section 1128(b)(15) to exclude individuals is not subject to administrative or judicial review.

The Shell Game

The OIG is also supporting legislation that would grant the OIG expanded authority to exclude from federal health care programs, parent corporations affiliated with companies convicted of Medicare fraud.28 This would eliminate the perceived practice of propping up a shell company to insulate the parent company from liability. In a June hearing before the House Ways and Means Health Subcommittee, the Chief Counsel for the OIG testified:

Establishing accountability is challenging in part because corporations sometimes intentionally construct byzantine structures that obscure responsible parties from view. OIG has seen a variety of methods used to conceal true ownership, including establishing shell corporations, creating limited liability companies (LLC) to manage operations . . . creating LLCs for real estate holdings, and creating affiliated corporations to lease and sublease among the various inter-owned corporations.29

The legislation authorizes the OIG to exclude "an entity affiliated with such sanctioned entity." For purposes of this bill, "affiliation" is a sweeping connector. For example, entities would be considered affiliated if one of the entities is a person with an ownership or control interest in the other entity or if there is a person who is an officer or managing employee of both entities.

However, even if the OIG is given such sweeping authority, it is unlikely it will choose to utilize this practice with all violators, as the OIG may believe the collateral consequences to excluding a large corporation will involve more harm than good for Medicare and Medicaid recipients.30 As such, the result may be that the OIG excludes individuals in a position to influence the corporation while leaving the corporation free to continue its business.31

26 Strengthening Medicare Anti-Fraud Measures Act ("H.R. 6130") Introduced by Rep. Fortney Pete Stark (D-CA), Chairman of the House Ways and Means Health Subcommittee, and Wally Herger (R-CA), Ranking Member of that subcommittee.

27 Id.

28 Id.


30 See Drew Griffin & Andy Seage, Feds Found Pfizer Too Big to Nail, CNN, April 2, 2010.; See also Medicare and Medicaid Extenders Act of 2010 (Pub. L. 111-309) repealing mandatory exclusion provision requiring Medicaid agencies to exclude an individual or entity that "owns, controls, or manages" a Medicaid-participating entity that is affiliated with an individual or entity that has been suspended or excluded from participation in Medicaid.

31 See K-V Pharmaceutical Company Press Release, Board of Directors Announces Permanent Chief Executive Officer Company Announces Resignation of Marc S. Hermelin from Board, Nov. 17, 2010 available at http://www.kvpharmaceutical.com/news_center/article.aspx?articleid=229[discussing Mr. Hermelin’s exclusion and stating “In an effort to avoid adverse consequences to the Company, including a discretionary exclusion of the Company, and to enable the Company to secure its expanded financial agreement with the Lenders, Mr. Hermelin has voluntarily resigned his position on the Company’s Board of Directors effective November 10, 2010. Mr. Hermelin has also resigned as trustee of all family trusts that hold K-V stock and has agreed to divest his personal ownership interests in the company’s Class A Common and Class B Common stock (approximately 1.8 million shares) over an agreed upon period of time in accordance with a divestiture plan and schedule approved by HHS OIG as part of a broader and recently executed settlement agreement (the “Settlement Agreement”) by and among HHS OIG, Mr. Hermelin, his wife, and the Company.]
Conclusion

Exclusion for an individual may effectively be a career death sentence as it would likely preclude such individual from employment in any capacity by any entity that receives reimbursements directly or indirectly from any federal health care program.

As the individual focus intensifies, it would certainly be advisable for individuals and entities to reassess the strength of their compliance programs and their level of involvement in compliance efforts.