

OIG Publishes Solicitation for Comments on New and Modified Safe Harbors Under the Federal Anti-Kickback Statute and New OIG Special Fraud Alerts; Proposals Due by 2/27/12

by Leah A. Roffman

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On December 29, 2011, the Office of Inspector General of the Department of Health and Human Services (“OIG”) published its annual notice (“Solicitation”) soliciting recommendations and proposals for developing new and modifying existing safe harbors under the Federal Anti-Kickback Statute¹ (“Anti-Kickback Statute”) and developing new OIG Special Fraud Alerts.² Proposals must be submitted by February 27, 2012, to the OIG.³

The Anti-Kickback Statute’s Safe Harbor Provisions

The Anti-Kickback Statute provides that whoever knowingly and willfully offers, pays, solicits, or receives remuneration to induce or reward business reimbursable under the federal health care programs will be guilty of a felony punishable by fines of up to \$25,000 and imprisonment for up to five years.⁴ Additional penalties may include civil money penalties⁵ and exclusion from the federal health care programs.⁶ In order to limit the number of legitimate and innocuous business arrangements that may qualify as kickbacks pursuant to the Anti-Kickback Statute, the OIG developed safe harbor provisions. Health care providers and others may structure arrangements with referral sources that would otherwise violate the Anti-Kickback Statute to comply with either a

¹ 42 U.S.C. §1320a-7b(b).

² 76 Fed. Reg. 81904 (Dec. 29, 2011).

³ Electronic comments may be submitted at <http://www.regulations.gov>. Written comments may be mailed to the following address: Office of Inspector General, Congressional and Regulatory Affairs, Department of Health and Human Services, Attention: OIG-120-N, Room 5541, Cohen Building, 330 Independence Avenue, S.W., Washington, DC 20201.

⁴ *Id.*

⁵ 42 U.S.C. §1320a-7a(a)(7).

⁶ 42 U.S.C. §1320a-7(b)(7).

statutory exception⁷ or a safe harbor provision in order to avoid liability under the Anti-Kickback Statute. To ensure that the list of safe harbor provisions remains current with evolving health care industry practices, Section 205 of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”)⁸ requires the OIG to develop and publish an annual notice in the *Federal Register* soliciting proposals for developing new and modifying existing safe harbors to the Anti-Kickback Statute.

The OIG will analyze various factors when reviewing proposals for new or modified safe harbor provisions. Such considerations include how each proposal may impact:

- access to, and/or the quality of, health care services;
- competition between, and patient choice among, providers;
- the cost to federal health care programs;
- the potential overutilization of health care services;
- the provision of health care services in medically underserved areas or to medically underserved populations; and
- the potential financial benefit to health care professionals that may affect their decisions to (1) order a health care item or service or (2) arrange for a referral of health care items or services to a specific provider.

OIG Special Fraud Alerts

The Solicitation also seeks proposals for developing new OIG Special Fraud Alerts. The OIG has issued such alerts periodically over time for the benefit of the health care community in order to identify certain practices that the OIG considers to be potentially fraudulent or abusive. Providers utilize these alerts as instructive and to assist with structuring arrangements, and federal health care program administrators also use these alerts to gauge whether provider practices are compliant and appropriate. HIPAA requires the OIG to solicit proposals for new OIG Special Fraud Alerts annually. This requirement is designed to ensure that the industry will have a recurring opportunity to seek clarification regarding what constitutes fraudulent behavior. The OIG will evaluate submissions by considering the extent to which a practice identified in a new potential OIG Special Fraud Alert might impact any of the factors described above.

Considerations

Participants in all segments of the health care community should consider responding to the Solicitation. Recent legislative, judicial, and regulatory developments have altered the health care delivery marketplace such that relationships between and arrangements among health care entities have changed substantially. Therefore, the opportunity is ripe to consider ways in which a new or modified safe harbor may be merited or guidance in the form of an OIG Special Fraud Alert may be timely and prove useful for the industry. Proposals for new or modified safe harbor provisions as well as

⁷ 42 U.S.C. §1320a-7(b)(b)(3).

⁸ 42 U.S.C. §1320a-7D.

suggestions for new OIG Special Fraud Alerts must be submitted to the OIG electronically, by mail, or by hand in advance of the February 27, 2012, deadline.

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*This Client Alert was authored by **Leah A. Roffman**. For additional information about the issues discussed in this Client Alert, please contact one of the authors or the Epstein Becker Green attorney who regularly handles your legal matters.*

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