



HHS' OIG Solicitation of New Safe Harbors and Special Fraud Alerts

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The Department of Health and Human Service's Office of the Inspector General (OIG) published a notice in the *Federal Register* on December 30, 2014 seeking comments on potential new safe harbors as well as the possible modification of existing safe harbor under the federal anti-kickback statute of the Social Security Act.

Section 1128B(b) of the Social Security Act provides for criminal penalties for individuals or entities that "knowingly and willfully offer, pay, solicit, or receive remuneration to induce or reward business reimbursable under the federal health care programs." The statute on its face is quite broad, and concern has been expressed that some relatively innocuous commercial arrangements may be subject to criminal prosecution or administrative sanction. To address this concern, section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987 specifically required the development and promulgation of regulations, also known as "safe harbor" provisions, that specify various payment and business practices that, while potentially capable of inducing referrals of business reimbursable under the federal health care programs, would not be treated as criminal offenses under the anti-kickback statute and would not serve as a basis for administrative sanctions. The OIG safe harbor provisions have been developed to limit the reach of the statute by permitting certain non-abusive arrangements, while encouraging beneficial and innocuous arrangements.

In addition, the OIG periodically issues Special Fraud Alerts to provide continuing guidance to health care providers with respect to practices that OIG finds potentially fraudulent or abusive. These alerts are intended for extensive distribution directly to health care providers, as well as to those charged with administering federal health care programs.

The OIG now seeks detailed suggestions for new safe harbors, justifications for modifications of existing safe harbors, and suggestions for Special Fraud Alerts. The OIG will consider a number of factors in reviewing proposals for new or modified safe harbor provisions, such as the extent to which the proposals would affect an increase or decrease in the following:

- Access to health care services;
- The quality of health care services;
- Patient freedom of choice among health care providers;
- Competition among health care providers;
- The cost the federal health care programs;
- The potential overutilization of health care services, and
- The ability of health care facilities to provide services in medically underserved areas or to medically underserved populations.

The OIG also will consider other factors, such as the existence (or nonexistence) of any potential financial benefit to health care professionals that may take into account their decisions to order health care items or services or arrange for a referral of health care items or services to a particular practitioner or provider. The OIG will consider whether, and to what extent, the practices that would be identified in a new Special Fraud Alert may result in any of the consequences set forth above, as well as the volume and frequency of the conduct that would be identified in the Special Fraud Alert.

Comments are due no later than February 28, 2015.

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