

## OIG SOLICITS PROPOSALS FOR THE DEVELOPMENT AND MODIFICATION OF ANTI-KICKBACK STATUTE SAFE HARBORS AND SPECIAL FRAUD ALERTS

On December 9, 2025, the Department of Health and Human Services' ("HHS") Office of the Inspector General ("OIG") issued its **annual solicitation** for proposals and recommendations for developing new or modifying existing Anti-Kickback Statute ("AKS") safe harbor provisions. In doing so, the OIG's objective is to identify safe harbors that safeguard "beneficial and innocuous arrangements" and to protect federal health care programs and their beneficiaries from "the harms caused by fraud and abuse." The solicitation also seeks proposals for developing new OIG Special Fraud Alerts.

### BACKGROUND

The AKS imposes criminal sanctions for individuals and entities that knowingly and willfully offer, pay, solicit or receive remuneration to induce or reward referrals or the generation of federal health care program business. Due to the breadth of the AKS, the OIG has promulgated numerous safe harbors protecting various payment and business practices from sanctions under the AKS. The OIG also has the authority to create new and/or modify existing AKS safe harbors from time to time.

The OIG periodically publishes Special Fraud Alerts to provide guidance to health care industry stakeholders regarding practices the OIG considers suspect or particularly concerning.

Section 205 of the Health Insurance Portability and Accountability Act and Section 1128D of the Social Security Act (42 U.S.C. 1320a-7d) mandate that HHS annually solicit proposals for developing new and modifying existing AKS safe harbors and for issuing Special Fraud Alerts.

### PROPOSAL CRITERIA

#### In General

OIG encourages proposals to include detailed explanations to justify, or empirical data to support, suggestions for new or modified safe harbors or for issuance of a new Special Fraud Alert.

#### AKS Safe Harbors

With respect to modifying and establishing AKS safe harbors, OIG will consider factors such as the extent to which the proposal results in an increase or decrease in:

- 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 to 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.

OIG will also consider other factors, including whether or not the proposed safe harbor or modification includes a potential financial benefit to health care professionals or providers that may influence their decision whether to (1) order a health care item or service; or (2) arrange for a referral of health care items or services to a particular practitioner or provider.

#### Special Fraud Alerts

With respect to developing Special Fraud Alerts, OIG will consider whether and to what extent the practices addressed in a new Special Fraud Alert may lead to any of the factors listed above, as well as the volume and frequency of the conduct identified in the Alert.

## **PRACTICAL TAKEAWAYS**

This is an opportunity for health care stakeholders to provide input on certain key statutory and regulatory guidelines. For example, providers may consider suggestions based on experience with the new value-based enterprise safe harbors or challenges facing their organizations. Any modifications or enhancements to the AKS safe harbor can have far-reaching implications across the health care industry, and any new Special Fraud Alerts can shed light on suspect practices as well as encourage proactive compliance. To ensure consideration, **comments are due by 5:00 PM on February 9, 2026**. Comments may be submitted electronically or by regular, express or overnight mail.

If you would like assistance in considering potential suggestions, responding to this solicitation or would like additional information on these topics, please contact:

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