



Office of Inspector General

42 CFR Part 1001

Solicitation of New Safe Harbors and Special Fraud Alerts

AGENCY: Office of Inspector General (OIG), Department of Health and Human Services (HHS).

ACTION: Notification of intent to develop regulations.

SUMMARY: In accordance with section 205 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), this annual notification solicits proposals and recommendations for developing new, or modifying existing, safe harbor provisions under section 1128B(b) of the Social Security Act (the Act), the Federal anti-kickback statute, as well as developing new OIG Special Fraud Alerts.

DATES: To ensure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on [insert date 60 days after publication in the *Federal Register*].

ADDRESSES: In commenting, please refer to file code OIG-128-N. Because of staff and resource limitations, we cannot accept comments by facsimile (fax) transmission. You may submit comments in one of three ways (no duplicates, please):

1. Electronically. You may submit electronic comments on specific recommendations and proposals through the Federal eRulemaking Portal at <http://www.regulations.gov>.

2. By regular, express, or overnight mail. You may send written comments to the following address: OIG, Regulatory Affairs, HHS, Attention: OIG-1117-N, Room 5527, Cohen Building, 330 Independence Avenue, SW, Washington, DC 20201. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By hand or courier. If you prefer, you may deliver your written comments by hand or courier before the close of the comment period to the following address: OIG, HHS, Cohen Building, Room 5527, 330 Independence Avenue, SW, Washington, DC 20201. Because access to the interior of the Cohen Building is not readily available to persons without Federal Government identification, commenters are encouraged to schedule their delivery with one of our staff members at officeofcounsel@oig.hhs.gov. For information on the inspection of public comments, please see the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Samantha Flanzer, Office of Inspector General, (202) 619-0335.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on recommendations for developing new or revised safe harbors and Special Fraud Alerts. Please assist us by referencing the file code OIG-1117-N.

Inspection of Public Comments: All comments received before the end of the comment period will be posted for public viewing at

[http:// www.regulations.gov](http://www.regulations.gov).

I. Background

A. OIG Safe Harbor Provisions

Section 1128B(b) of the Act, (42 U.S.C. 1320a-7b(b), the Federal anti-kickback statute), provides for criminal penalties for whoever knowingly and willfully offers, pays, solicits, or receives remuneration to induce or reward, among other things, the referral for, or purchase of, items or services reimbursable under any of the Federal health care programs, as defined in section 1128B(f) of the Act (42 U.S.C. 1320a-7b(f)). The offense is classified as a felony and is punishable by fines of up to \$100,000 and imprisonment for up to 10 years. Violations of the Federal anti-kickback statute also may result in the imposition of civil monetary penalties under section 1128A(a)(7) of the Act (42 U.S.C. 1320a-7a(a)(7)), program exclusion under section 1128(b)(7) of the Act (42 U.S.C. 1320a-7(b)(7)), and liability under the False Claims Act (31 U.S.C. 3729-33).

Because of the broad reach of the statute, concern was expressed that some relatively innocuous business arrangements were covered by the statute and, therefore, potentially subject to criminal prosecution. In response, Congress enacted section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100-93 (note to section 1128B of the Act; 42 U.S.C. 1320a-7b), which specifically requires the development and promulgation of regulations, the so-called safe harbor provisions, that would specify various payment and

business practices that would not be subject to sanctions under the Federal anti-kickback statute, even though they potentially may be capable of inducing referrals of business for which payment may be made under a Federal health care program. Since July 29, 1991, there have been a series of final regulations published in the *Federal Register* establishing safe harbors protecting various payment and business practices.¹ These safe harbor provisions have been developed "to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial and innocuous arrangements."² Health care providers and others may voluntarily seek to comply with the conditions of an applicable safe harbor so that they have the assurance that their payment or business practice will not be subject to sanctions under the Federal anti-kickback statute. The safe harbor regulations promulgated by OIG are found at 42 CFR part 1001.

B. OIG Special Fraud Alerts

OIG periodically issues Special Fraud Alerts to give continuing guidance to health care industry stakeholders regarding practices OIG considers to be suspect or of particular concern.³ The Special Fraud Alerts encourage industry compliance

¹ See e.g., Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 FR 88368 (Dec. 7, 2016).

² Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 FR 35952, 35958 (July 29, 1991).

³ See e.g., Special Fraud Alert: Speaker Programs (Nov. 16, 2020), available at

by giving stakeholders guidance that can be applied to their own practices. OIG Special Fraud Alerts are published in the *Federal Register* and on OIG's website and are intended for extensive distribution.

In developing Special Fraud Alerts, OIG relies on a number of sources and consults directly with experts in the subject field, including those within OIG, other agencies of HHS, other Federal and State agencies, and those in the health care industry.

C. Section 205 of the Health Insurance Portability and Accountability Act of 1996

Section 205 of HIPAA, Public Law 104-191, and section 1128D of the Act (42 U.S.C. 1320a-7d), requires the Department to develop and publish an annual notification in the *Federal Register* formally soliciting proposals for developing additional or modifying existing safe harbors to the Federal anti-kickback statute and Special Fraud Alerts.

In developing or modifying safe harbors under the Federal anti-kickback statute, OIG, in consultation with the Department of Justice, thoroughly reviews the range of factual circumstances that may receive protection by the proposed or modified safe harbor. In doing so, OIG seeks to identify and develop regulatory limitations and controls in order to permit beneficial and innocuous arrangements while, at the same time,

protecting Federal health care programs and their beneficiaries from the harms caused by fraud and abuse.

II. Solicitation of Additional New Recommendations and Proposals

OIG seeks recommendations regarding the development of additional or modified safe harbor regulations and new Special Fraud Alerts. A detailed explanation of justifications for, or empirical data supporting, a suggestion for a new or modified safe harbor or Special Fraud Alert would be helpful and should, if possible, be included in any response to this solicitation.

A. Criteria for Modifying and Establishing Safe Harbor Provisions

In accordance with section 205 of HIPAA, we will consider a number of factors in reviewing proposals for additional or modified safe harbor provisions, such as the extent to which the proposals would affect 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.

In addition, we will consider other factors, including, for example, the existence (or nonexistence) of any 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.

B. Criteria for Developing Special Fraud Alerts

In determining whether to issue additional Special Fraud Alerts, we 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.

Dated: November 19, 2020.

Christi A. Grimm,

Principal Deputy Inspector General.

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