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## MEMORANDUM

January 17, 2014

TO: Tribal Health Clients

FROM: Hobbs, Straus, Dean & Walker, LLP

Re: *Status update on anti-kickback statute safe harbor provisions for Indian health providers*

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The federal Anti-Kickback Statute (AKS) imposes civil and criminal penalties upon anyone who “knowingly and willfully solicits or receives any remuneration” in return for a referral under a federal health care program. 42 U.S.C. §§ 1320a-7a(a)(7), 1320a-7b(b). The statute’s broad application prompted Congress to require that the Department of Health and Human Services (HHS) promulgate regulations, referred to as “safe harbor” provisions, exempting certain programs or business practices from the application of the statute. See 42 U.S.C. § 1320a-7b(b)(3)(E).

HHS’s Office of the Inspector General (OIG) has created a list of safe harbors, and each year OIG solicits recommendations for additional safe harbors. See 42 C.F.R. § 1001.952. For instance, in 2007 OIG amended its regulations to provide a safe harbor for certain arrangements involving Federally Qualified Health Centers (FQHCs). 42 C.F.R. § 1001.952(w). However, there is currently no safe harbor specific to Indian health care providers. A safe harbor modelled after the FQHC safe harbor would protect remuneration in the form, for instance, of discounts, goods, items, services, donations, and loans. This protection would allow Indian health care providers to enter into a variety of legitimate business arrangements that otherwise might run afoul of the AKS. For instance, a safe harbor specific to Indian health may enable tribes to ensure the availability of specialist services by allowing a specialist to use tribal clinical space in return for providing discounts to the tribe’s contract health services program.

In response to OIG’s December 2011 solicitation for proposals to develop or modify safe harbor provisions, we assisted the Tribal Technical Advisory Group (TTAG) and the National Indian Health Board (NIHB) to submit comments proposing several new safe harbors for Indian health care providers, including one modeled after the safe harbor provided to FQHCs. Like the FQHC safe harbor, this safe harbor for Indian health care providers would seek to exclude from the AKS remuneration that “furthers a core purpose of the Federal health centers program: ensuring the availability and quality of safety net health care services to otherwise underserved populations.” 72 Fed. Reg. 566632 (Oct. 4, 2007). Other safe harbors proposed by TTAG and NIHB included safe harbors for waivers of beneficiary coinsurance and deductible amounts, exchanges

among Indian health care providers, transfers from Indian health care providers to Indians eligible for or receiving the services of that provider, and arrangements to share facilities and resources among Indian health care providers and other health care providers.

OIG responded to the TTAG and NIHB proposals in its Fall 2012 Semiannual Report to Congress, stating that “OIG is considering whether to promulgate a safe harbor that would address the concerns described in this proposal.”<sup>1</sup> However, OIG has failed to take any action on this issue to date.

On December 27, 2013, OIG issued its latest solicitation for new safe harbors. 78 Fed. Reg. 78807 (Dec. 27, 2013). Because OIG has thus far failed to act, the TTAG may reiterate its request for a new safe harbor for Indian health care providers by submitting comments to OIG and will be requesting a meeting with OIG on this important issue. The deadline for public comments is 5 p.m. on February 25, 2014.

If you have questions about this report or would like assistance with drafting a comment to submit to OIG, please contact Elliott Milhollin at (202)822-8282 or [emilhollin@hobbsstrauss.com](mailto:emilhollin@hobbsstrauss.com); Geoff Strommer at (503)242-1745 or [gstrommer@hobbsstrauss.com](mailto:gstrommer@hobbsstrauss.com); or Starla Roels at (503)242-1745 or [sroels@hobbsstrauss.com](mailto:sroels@hobbsstrauss.com).

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<sup>1</sup> Office of the Inspector General, Semiannual Report to Congress April 2013–September 2013, Appendix F, p. 29, <http://oig.hhs.gov/reports-and-publications/archives/semiannual/2012/fall/sar-f12-fulltext.pdf>.

already reimbursed by the Medicare program.

\* \* \* \* \*

■ 8. Add a new § 405.947 to subpart I to read as follows:

**§ 405.947 Notice to the beneficiary of applicable plan's request for a redetermination.**

(a) The contractor adjudicating the redetermination request must send notice of the applicable plan's appeal to the beneficiary.

(b) Issuance and content of the notice must comply with CMS instructions.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 29, 2013.

**Marilyn Tavenner,**  
Administrator, Centers for Medicare & Medicaid Services.

Approved: November 12, 2013.

**Kathleen Sebelius,**  
Secretary, Department of Health and Human Services.

[FR Doc. 2013–30661 Filed 12–26–13; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of Inspector General**

**42 CFR Part 1001**

**Solicitation of New Safe Harbors and Special Fraud Alerts**

**AGENCY:** Office of Inspector General (OIG), HHS.

**ACTION:** Notice of intent to develop regulations.

**SUMMARY:** In accordance with section 205 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), this annual notice solicits proposals and recommendations for developing new and modifying existing safe harbor provisions under the Federal anti-kickback statute (section 1128B(b) of the Social Security Act), 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 February 25, 2014.

**ADDRESSES:** In commenting, please refer to file code OIG–122–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: Patrice Drew, Office of Inspector General, Congressional and Regulatory Affairs, Department of Health and Human Services, Attention: OIG–122–N, Room 5541C, 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, by hand or courier, your written comments before the close of the comment period to Patrice Drew, Office of Inspector General, Department of Health and Human Services, Cohen Building, Room 5541C, 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 (202) 619–1368. For information on viewing public comments, please see the Supplementary Information section.

**FOR FURTHER INFORMATION CONTACT:** Patrice Drew, Congressional and Regulatory Affairs Liaison, Office of Inspector General, (202) 619–1368.

**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–122–N.

*Inspection of Public Comments:* All comments received before the end of the comment period are available for viewing by the public. All comments will be posted on <http://www.regulations.gov> as soon as possible after they have been received.

Comments received timely will also be available for public inspection as they are received at Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue SW., Washington, DC 20201, Monday through Friday from 9:30 a.m. to 5 p.m. To schedule an appointment to view public comments, phone (202) 619–1368.

**I. Background**

*A. OIG Safe Harbor Provisions*

Section 1128B(b) of the Social Security Act (the Act) (42 U.S.C. 1320a–7b(b)) provides 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 offense is classified as a felony and is punishable by fines of up to \$25,000 and imprisonment for up to 5 years. OIG may also impose civil money penalties, in accordance with section 1128A(a)(7) of the Act (42 U.S.C. 1320a–7a(a)(7)), or exclusion from the Federal health care programs, in accordance with section 1128(b)(7) of the Act (42 U.S.C. 1320a–7(b)(7)).

Since the statute on its face is so broad, concern has been expressed for many years that some relatively innocuous commercial arrangements may be subject to criminal prosecution or administrative sanction. In response to the above concern, section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100–93 § 14, the Act, § 1128B(b), 42 U.S.C. 1320a–7b(b), specifically required the development and promulgation of regulations, the so-called “safe harbor” provisions, specifying various payment and business practices that, although 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. OIG 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” (56 FR 35952, July 29, 1991). Health care providers and others may voluntarily seek to comply with these provisions so that they have the assurance that their business practices will not be subject to liability under the anti-kickback statute or related administrative authorities. The OIG safe harbor regulations are found at 42 CFR 1001.952.

*B. OIG Special Fraud Alerts*

OIG has also periodically issued Special Fraud Alerts to give continuing guidance to health care providers with respect to practices OIG finds potentially fraudulent or abusive. The Special Fraud Alerts encourage industry compliance by giving providers guidance that can be applied to their own practices. OIG Special Fraud Alerts

are intended for extensive distribution directly to the health care provider community, as well as to those charged with administering the Federal health care programs.

In developing Special Fraud Alerts, OIG has relied on a number of sources and has consulted directly with experts in the subject field, including those within OIG, other agencies of the Department, 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 the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191 § 205, the Act, § 1128D, 42 U.S.C. 1320a-7d, requires the Department to develop and publish an annual notice in the **Federal Register** formally soliciting proposals for modifying existing safe harbors to the anti-kickback statute and for developing new safe harbors and Special Fraud Alerts.

In developing safe harbors for a criminal statute, OIG is required to engage in a thorough review of the range of factual circumstances that may fall within the proposed safe harbor subject area so as to uncover potential opportunities for fraud and abuse. Only then can OIG determine, in consultation with the Department of Justice, whether it can effectively develop regulatory limitations and controls that will permit beneficial and innocuous arrangements within a subject area while, at the same time, protecting the Federal health care programs and their beneficiaries from abusive practices.

**II. Solicitation of Additional New Recommendations and Proposals**

In accordance with the requirements of section 205 of HIPAA, OIG last published a **Federal Register** solicitation notice for developing new safe harbors and Special Fraud Alerts on December 28, 2012 (77 FR 76434). As required under section 205, a status report of the public comments related to safe harbors received in response to that notice is set forth in Appendix F to the OIG's Semiannual Report to Congress covering the period April 1, 2013, through September 30, 2013.<sup>1</sup> OIG is not seeking additional public comment on the proposals listed in Appendix F at this time. Rather, this notice seeks additional recommendations regarding the development of new or modified

safe harbor regulations and new Special Fraud Alerts beyond those summarized in Appendix F.

A detailed explanation of justifications for, or empirical data supporting, a suggestion for a 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 new 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 also take into consideration other factors, including, for example, the existence (or nonexistence) of any potential financial benefit to health care professionals or providers that may be taken into account in their decisions 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: December 17, 2013.

**Daniel R. Levinson,**  
*Inspector General.*

[FR Doc. 2013-30429 Filed 12-26-13; 8:45 am]

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**DEPARTMENT OF HOMELAND SECURITY**

**Federal Emergency Management Agency**

**44 CFR Part 67**

[Docket ID FEMA-2013-0002; Internal Agency Docket No. FEMA-B-7748]

**Proposed Flood Elevation Determinations for Pierce County, Washington, and Incorporated Areas**

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Proposed rule; withdrawal.

**SUMMARY:** The Federal Emergency Management Agency (FEMA) is withdrawing its proposed rule concerning proposed flood elevation determinations for Pierce County, Washington, and Incorporated Areas. **DATES:** The proposed rule published December 6, 2007, at 72 FR 68784, corrected April 16, 2012, at 77 FR 22551, is withdrawn effective December 27, 2013.

**ADDRESSES:** You may submit comments, identified by Docket No. FEMA-B-7748, to Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646-4064, or (email) *Luis.Rodriguez3@fema.dhs.gov*.

**FOR FURTHER INFORMATION CONTACT:** Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646-4064, or (email) *Luis.Rodriguez3@fema.dhs.gov*.

**SUPPLEMENTARY INFORMATION:** On December 6, 2007, FEMA published a proposed rulemaking at 72 FR 68784, proposing flood elevation determinations along one or more flooding sources in Pierce County, Washington. On April 16, 2012, FEMA published a proposed rulemaking at 77 FR 22551, proposing corrected flood elevation determinations along one or more flooding sources in Pierce County, Washington. Because FEMA has or will be issuing a Revised Preliminary Flood Insurance Rate Map, and if necessary a Flood Insurance Study report, featuring updated flood hazard information, the proposed rulemaking is being withdrawn. A Notice of Proposed Flood Hazard Determinations will be published in the **Federal Register** and in

<sup>1</sup> The OIG *Semiannual Report to Congress* can be accessed through the OIG Web site at <http://oig.hhs.gov/publications/semiannual.asp>.