

equal or exceed ten acres, (3) are located outside of the Big River Flood Plain Ecoregion and (4) are not listed as having site-specific criteria in Table M of the State's WQS.

(b) *Combined Criterion for Missouri lakes and reservoirs.* In all instances, nutrient protection values are maximum ambient concentrations expressed as seasonal (April through September)

geometric mean values on a three-year rolling average basis.

TABLE 1—LAKE ECOREGION NUTRIENT PROTECTION VALUES (µG/L) AND EUTROPHICATION IMPACTS \*

Lake Ecoregion	TP	TN	Chl-a
Plains .....	44	817	14
Ozarks .....	23	500	7.1

\* Table 1 also applies to tributary arms Grand Glaize, Gravois, and Nianga to the Lake of the Ozarks, and tributary arms James River, Kings River, and Long Creek to Table Rock Lake.

(1) Lake and reservoir water quality must not exceed nutrient protection values for chlorophyll *a*.

(2) Lake and reservoir water quality must also not exceed nutrient protection values for total nitrogen and total phosphorus unless each of the following eutrophication impacts are evaluated and none occur within the same three-year rolling average period: (I) Eutrophication-related mortality or morbidity events for fish and other aquatic organisms, (II) An excursion from the DO or pH criteria in Missouri water quality standards applicable for Clean Water Act purposes, (III) Cyanobacteria counts equal to or greater than 100,000 cells per ml, (IV) Observed shifts in aquatic diversity directly attributable to eutrophication, or (V) Excessive levels of mineral turbidity that consistently limit algal productivity during the period May 1—September 30, or Secchi disk measurements of turbidity equal to or less than EPA's recommended Level III Ecoregions IX (1.53 m) or IX (2.86 m).

(c) Applicability

(1) The combined criterion in paragraph (b) of this section applies to waters discussed in paragraph (a) of this section and applies concurrently with other applicable water quality criteria.

(2) The combined criterion established in this section is subject to Missouri's general rules of applicability in the same way and to the same extent as state-adopted and EPA-approved water quality criteria when applied to the waters discussed in paragraph (a).

(d) *Effective date.* Section 131.47 will be in effect [date 60 days after publication of final rule].

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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:** 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, and modifying existing, safe harbor provisions under the Federal anti-kickback statute (§ 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 26, 2018.

**ADDRESSES:** In commenting, please refer to file code OIG-127-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, Regulatory Affairs, Department of Health and Human Services, Attention: OIG-127-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 your written comments by hand or courier 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, 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-127-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> after the closing of the comment period. Comments received in a timely manner will also be available for public inspection as they are received at the Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue SW, Washington, DC 20201, Monday through Friday, from 10 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 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 Federal health care programs, in accordance with section 1128(b)(7) of the Act (42 U.S.C. 1320a-7(b)(7)).

Because 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, 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 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. OIG safe harbor regulations 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 providers with respect to practices OIG considers to be suspect or of particular concern. The Special Fraud Alerts encourage industry compliance by giving providers guidance that can be applied to their own practices. OIG Special Fraud Alerts are published in the **Federal Register** and on our 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 the U.S. Department of Health and Human

Services (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 notification 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 thoroughly reviews 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 U.S. 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 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 notification for developing new safe harbors and Special Fraud Alerts on December 28, 2016 (81 FR 95551). As required under section 205 of the Act, a status report of the proposals OIG received for new and modified safe harbors in response to that solicitation notification is set forth in Appendix F of OIG’s Fall 2017 *Semiannual Report to Congress*.<sup>1</sup> OIG is not seeking additional public comment on the proposals listed in Appendix F at this time. Rather, this notification 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

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

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 consider other factors, including, for example, the existence (or nonexistence) of any potential financial benefit to health care professionals or providers that may take into account 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 12, 2017.

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

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## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### 50 CFR Part 17

[Docket No. FWS-HQ-ES-2017-0047;  
4500090024]

RIN 1018-BC83

### Endangered and Threatened Wildlife and Plants; Listing the Yangtze Sturgeon as an Endangered Species

AGENCY: Fish and Wildlife Service, Interior.