

and willfully offer, pay, solicit or receive remuneration in order 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, the Medicare and Medicaid Patient and Program Protection Act of 1987, section 14 of Public Law 100-93, specifically required the development and promulgation of regulations, the so-called "safe harbor" provisions, specifying various payment and business practices which, 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.

Existing OIG safe harbors describing those practices that are sheltered from liability are codified in 42 CFR part 1001.

#### *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 these 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 Public Law 104-191*

Section 205 of Public Law 104-191 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 Public Law 104-191, OIG last published a **Federal Register** solicitation notice for developing new safe harbors and Special Fraud Alerts on December 11, 2006 (71 FR 71501). As required under section 205, a status report of the public comments received in response to that notice is set forth in Appendix D to the OIG's Semiannual Report covering the period April 1, 2007, through September 30, 2007.<sup>1</sup> OIG is not seeking additional public comment on the proposals listed in Appendix D at this time. Rather, this notice seeks additional recommendations regarding the development of proposed or modified safe harbor regulations and new Special Fraud Alerts beyond those summarized in Appendix D to the OIG Semiannual Report referenced above.

#### *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

<sup>1</sup> The OIG Semiannual Report can be accessed through the OIG web site at <http://oig.hhs.gov/publications/semiannual.html>.

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 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 the 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 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 also 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.

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.

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

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## **DEPARTMENT OF THE INTERIOR**

### **Fish and Wildlife Service**

#### **50 CFR Part 20**

#### **Service Regulations Committee Meeting**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of meeting.

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**SUMMARY:** The Fish and Wildlife Service (hereinafter Service) will conduct an open meeting on January 30, 2008, to identify and discuss preliminary issues concerning the 2008–09 migratory bird hunting regulations.

**DATES:** The meeting will be held January 30, 2008.

**ADDRESSES:** The Service Regulations Committee will meet at the Embassy Suites Hotel, Denver—International Airport, 7001 Yampa Street, Denver, Colorado, (303) 574–3000.

**FOR FURTHER INFORMATION CONTACT:** Robert Blohm, Chief, Division of Migratory Bird Management, U.S. Fish and Wildlife Service, Department of the Interior, ms–4107–ARLSQ, 1849 C

Street, NW., Washington, DC 20240, (703) 358–1714.

**SUPPLEMENTARY INFORMATION:** Under the authority of the Migratory Bird Treaty Act (16 U.S.C. 703–712), the U.S. Fish and Wildlife Service regulates the hunting of migratory game birds. We update the migratory game bird hunting regulations, located at 50 CFR part 20, annually. Through these regulations, we establish the frameworks, or outside limits, for season lengths, bag limits, and areas for migratory game bird hunting. To help us in this process, we have administratively divided the nation into four Flyways (Atlantic, Mississippi, Central, and Pacific), each of which has a Flyway Council. Representatives from the Service, the

Service’s Migratory Bird Regulations Committee, and Flyway Council Consultants will meet on January 30, 2008, at 8:30 a.m. to identify preliminary issues concerning the 2008–09 migratory bird hunting regulations for discussion and review by the Flyway Councils at their March meetings.

In accordance with Departmental policy regarding meetings of the Service Regulations Committee attended by any person outside the Department, these meetings are open to public observation.

**Paul R. Schmidt,**

*Assistant Director, Migratory Birds, U.S. Fish and Wildlife Service.*

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