

behalf of the participant plus \$1,000 for each unserved month.

(b) Participants who sign a continuation contract for any year beyond the initial two-year period and fail to complete the one-year period specified are liable for the pro rate amount of any benefits advanced beyond the period of completed service plus an amount equal to the number of months of obligated service that were not completed by the participant multiplied by \$1,000.

(c) Payments of any amount owed under paragraph (a) or (b) of this section shall be made within one year of the participant's breach (or such longer period as determined by the Secretary).

(d) Terminations will not be considered a breach of contract in cases where such terminations are beyond the control of the participant as follows:

(1) Terminations for cause or for convenience of the Government that are not based upon a breach or default of the participant will not be considered a breach of contract and monetary damages will not be assessed.

(2) The participant transfers to another NICHD intramural laboratory or eligible NICHD-supported extramural site, in which case the participant remains bound to any and all obligations of the contract.

(3) The participant transfer to a site other than an NICHD intramural laboratory or eligible NICHD-supported extramural site, in which case the participant may not be assessed monetary penalties if, in the judgment of the CIR-LRP Panel, the participant continues to engage in contraception and/or infertility research for any remaining period of obligated service as set forth in the contract.

§ 68c.13 Under what circumstances can the service or payment obligation be canceled, waived, or suspended?

(a) Any obligation of a participant for service or payment to the Federal Government under this part will be canceled upon the death of the participant.

(b)(1) The Secretary may waive or suspend any service or payment obligation incurred by the participant upon request whenever compliance by the participant:

- (i) Is impossible;
- (ii) Would involve extreme hardship to the participant; or
- (iii) If enforcement of the service or payment obligation would be against equity and good conscience.

(2) The Secretary may approve a request for a suspension of the service or payment obligations for a period of 1 year. A renewal of this suspension may also be granted.

(c) Compliance by a participant with a service or payment obligation will be considered impossible if the Secretary determines, on the basis of information and documentation as may be required, that the participant suffers from a physical or mental disability result in the permanent inability of the participant to perform the service or other activities which would be necessary to comply with the obligation.

(d) In determining whether to waive or suspend any or all of the service or payment obligations of a participant as imposing an undue hardship and being against equity and good conscience, the Secretary, on the basis of information and documentation as may be required, will consider:

- (1) The participant's present financial resources and obligations;
- (2) The participant's estimated future financial resources and obligations;
- (3) The extent to which the participant has problems of a personal nature, such as a physical or mental disability or terminal illness in the immediate family, which so intrude on the participant's present ability to perform as to raise a presumption that the individual will be unable to perform the obligation incurred.

§ 68c.14 When can a CIR-LRP payment obligation be discharged in bankruptcy?

Any payment obligation incurred under § 68c.12 may be discharged in bankruptcy under Title 11 of the United States Code only if such discharge is granted after the expiration of the five-year period beginning on the first date that payment is required and only if the bankruptcy court finds that a nondischarge of the obligation would be unconscionable.

§ 68c.15 Additional conditions.

In order to protect or conserve Federal funds or to carry out the purposes of section 487B of the Act, or of this part, the Secretary may impose additional conditions as a condition of any approval, waiver or suspension authorized by this part.

§ 68c.16 What other regulations and statutes apply?

Several other regulations and statutes apply to this part. These include, but are not necessarily limited to:

Debt Collection Act of 1982, Public Law 97-365 (5 U.S.C. 5514).

Fair Credit Reporting Act (15 U.S.C. 1681 et seq.).

Federal Debt Collection Procedures Act of 1990, Public Law 101-647(28 U.S.C. 1).

Privacy Act of 1974 (5 U.S.C. 552a).

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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: Intent to develop regulations.

SUMMARY: In accordance with section 205 of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, this annual document solicits proposals and recommendations for developing new and modifying existing safe harbor provisions under the Federal and State health care programs' anti-kickback statute, as well as developing new OIG Special Fraud Alerts.

DATES: To assure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on February 8, 2000.

ADDRESSES: Please mail or deliver your written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG-41-N, Room 5246, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201.

We do not accept comments by facsimile (FAX) transmission. In commenting, please refer to file code OIG-41-N. Comments received timely will be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, in Room 5541 of the Office of Inspector General at 330 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8 a.m. to 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Joel Schaer, (202) 619-0089, OIG Regulations Officer.

SUPPLEMENTARY INFORMATION:

I. Background

A. The 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 in order to induce business reimbursed under the Federal or State 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. The OIG may also impose administrative

sanctions or exclude violators from the Federal or State health care programs.

The types of remuneration covered specifically include kickbacks, bribes, and rebates, whether made directly or indirectly, overtly or covertly, or in cash or in kind. In addition, prohibited conduct includes not only remuneration intended to induce referrals of patients, but remuneration intended to induce the arranging for or the purchasing, leasing or ordering of any good, facility, service, or item paid for by Federal or State health care programs.

Since the statute on its face is so broad, concern has been expressed for many years that some relatively innocuous commercial arrangements are technically covered by the statute and are, therefore, subject to criminal prosecution. As a 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, designed to specify various payment and business practices which, although potentially capable of inducing referrals of business under the Federal and State health care programs, would not be treated as criminal offenses under the anti-kickback statute (section 1128B(b) of the Act; 42 U.S.C. 1320a-7b(b)) and would not serve as a basis for a program exclusion under section 1128(b)(7) of the Act; 42 U.S.C. 1320a-7(b)(7). The 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 are not subject to any enforcement action under the anti-kickback statute or program exclusion authority.

To date, the OIG has developed and codified in 42 CFR 1001.952 a total of 21 final safe harbors that describe practices that are sheltered from liability. The OIG is also currently developing a proposed safe harbor rule addressing ambulance restocking arrangements.

B. OIG Special Fraud Alerts

In addition, the OIG has also periodically issued Special Fraud Alerts to give continuing guidance to health care providers with respect to practices the OIG regards as unlawful. These Special Fraud Alerts serve to notify the health care industry that the OIG has become aware of certain abusive

practices that the OIG plans to pursue and prosecute, or to bring civil and administrative action, as appropriate. The Special Fraud Alerts also serve as a tool to encourage industry compliance by giving providers an opportunity to examine their own practices. The OIG Special Fraud Alerts are intended for extensive distribution directly to the health care provider community, as well as those charged with administering the Medicare and Medicaid programs.

In developing these Special Fraud Alerts, the OIG has relied on a number of sources and has consulted directly with experts in the subject field, including those within the OIG, other agencies of the Department, other Federal and State agencies, and those in the health care industry. To date, ten individual Special Fraud Alerts have been issued by the OIG and subsequently reprinted in the **Federal Register**.¹

C. Section 205 of Public Law 104-191

In accordance with the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191), the Department is now required to provide additional formal guidance regarding the application of the anti-kickback statute and the safe harbor provisions, as well as other OIG health care fraud and abuse sanctions. In addition to accepting and responding to requests for advisory opinions from outside parties regarding the interpretation and applicability of certain statutes relating to the Federal and State health care programs, 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 accordance with this requirement, the OIG has published notices in the **Federal Register** on December 31, 1996 (61 FR 69060); December 10, 1997 (62 FR 65049) and December 7, 1998 (63 FR 67486), soliciting such proposals.

In developing safe harbors for a criminal statute, the OIG is compelled to engage in a complete and thorough review of the range of factual circumstances that may fall within the proposed safe harbor subject area so as to uncover all potential opportunities

for fraud and abuse. Only then can the 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, the OIG is continuing to study safe harbor and Special Fraud Alert proposals submitted in response to the annual solicitations. Some of those suggestions have been addressed in the safe harbor rulemakings recently published on November 19, 1999 (64 FR 63504 and 64 FR 63518) or are already under development. In response to the previously-issued **Federal Register** solicitation notices, a status report of the public comments received for new and modified safe harbors is set forth annually in an appendix to the OIG's Semiannual Report covering the period April through September.² The OIG is currently taking the recommendations listed in the appendix under advisement and is not seeking additional public comment on those proposals at this time. Rather, this notice seeks additional recommendations from affected provider, practitioner, supplier and beneficiary representatives regarding the development of proposed or modified safe harbor regulations and new Special Fraud Alerts beyond those summarized in the appendix to the OIG Semiannual Report referenced above.

Criteria for Modifying and Establishing Safe Harbor Provisions

In accordance with the statute, 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 effect an increase or decrease in—

- Access to health care services;
- The quality of 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 the health care services; and
- The ability of health care facilities to provide services in medically

¹ See 59 FR 65372 (December 19, 1994); 60 FR 40847 (August 10, 1995); 61 FR 30623 (June 17, 1996); 63 FR 20415 (April 24, 1998); and 64 FR 1813 (January 12, 1999). The OIG has also issued three Special Advisory Bulletins—64 FR 37985 (July 14, 1999); 64 FR 52791 (September 30, 1999); and 64 FR 61353 (November 10, 1999).

² The OIG Semiannual Report can be accessed through the OIG web site at <http://www.dhhs.gov/oig/semann/index.htm>.

underserved areas or to medically underserved populations.

In addition, we will also take into consideration the existence (or nonexistence) of any potential financial benefit to health care professionals or providers that may vary based on 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.

Criteria for Developing Special Fraud Alerts

In determining whether to issue additional Special Fraud Alerts, we will also consider whether, and to what extent, those practices that would be identified in new Special Fraud Alerts may result in any of the consequences set forth above, and the volume and frequency of the conduct that would be identified in these Special Fraud Alerts.

A detailed explanation of justifications or empirical data supporting the suggestion, and sent to the address indicated above, would prove helpful in our considering and drafting new or modified safe harbor regulations and Special Fraud Alerts.

Dated: November 29, 1999.

June Gibbs Brown,

Inspector General.

[FR Doc. 99-32025 Filed 12-9-99; 8:45 am]

BILLING CODE 4150-04-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[I.D. 113099B]

RIN 0648-AL30

Fisheries of the Exclusive Economic Zone Off Alaska; Prohibition of Nonpelagic Trawl Gear in the Bering Sea and Aleutian Islands Directed Pollock Fishery

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of availability; request for comments.

SUMMARY: The North Pacific Fishery Management Council (Council) has submitted Amendment 57 to the Fishery Management Plan (FMP) for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area (BSAI). This amendment would prohibit the use of nonpelagic trawl gear in the directed pollock fishery in the BSAI. Comments from the public are requested.

DATES: Comments on Amendment 57 must be submitted by February 8, 2000.

ADDRESSES: Comments on the FMP amendments should be submitted to Sue Salvesson, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region, NMFS, P.O. Box 21668, Juneau, AK 99802, Attn: Lori Gravel. Comments may also be hand delivered or sent by courier to the Federal Building, 709 West 9th Street, Juneau, AK. Copies of Amendment 57 and the Environmental Assessment/Regulatory Impact Review/Initial Flexibility Analysis prepared for the amendment by the Council and NMFS are available from the North Pacific Fishery Management Council, 605 West 4th Ave., Suite 306, Anchorage, AK 99501-2252; telephone 907-271-2809. Comments will not be accepted if submitted via e-mail or Internet.

FOR FURTHER INFORMATION CONTACT:

Nina Mollett, 907-586-7462 or nina.mollett@noaa.gov.

SUPPLEMENTARY INFORMATION: The Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) requires that each Regional Fishery Management Council submit any FMP or FMP amendment it prepares to NMFS for review and approval, disapproval, or partial approval. The Magnuson-Stevens Act also requires that NMFS, upon receiving an FMP, immediately publish a notice in the **Federal Register** that the FMP or amendment is available for public review and comment.

The Council adopted Amendment 57 at its June 1998 meeting. If approved by NMFS, this amendment would prohibit the use of nonpelagic trawl gear in the directed pollock fishery in the BSAI and would reduce the bycatch limit of red king crab by 3,000 animals. The Council also recommended limits for other protected species, including halibut, *C. opilio* crab, and *C. bairdi*. NMFS may propose lowering these limits in a future proposed rule to implement Amendment 57. Amendment 57 is necessary to comply with the Magnuson-Stevens Act mandate that Regional Councils must take measures to reduce bycatch in the Nation's fisheries.

Public comments are being solicited on the amendment through the end of the comment period stated in this NOA; a proposed rule that would implement the amendment may be published in the **Federal Register** for public comment following NMFS' evaluation under the Magnuson-Stevens Act procedures. Public comments on the proposed rule must be received by the end of the comment period on the amendment in order to be considered in the approval/disapproval decision on the amendment. All comments received by the end of the comment period on the amendment, whether specifically directed to the amendment or to the proposed rule, will be considered in the approval/disapproval decision; comments received after that date will not be considered in the approval/disapproval decision on the amendment. To be considered, comments must be received by close of business on the last day of the comment period specified in this NOA; that does not mean postmarked or otherwise transmitted by that date.

Dated: December 6, 1999.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 99-32090 Filed 12-9-99; 8:45 am]

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