ESD, is required at the Site. Further, EPA has concluded that the 1996 ROD's ''No Further Action'' alternative's use of engineering and institutional controls at the Site will not interfere with the redevelopment and expansion objectives set forth in the October 1990 Master Plan Harrisburg International Airport commissioned by PennDOT's Bureau of Aviation's State-owned Airports Division.

On August 21, 1996, EPA and PADEP conducted a final inspection of the sentinel well construction. No deficiencies were noted nor were additional activities deemed necessary as a result of the inspection.

All remedial actions for this Site are complete. Collection of monitoring well data from the HIA production wells and the North Base Landfill sentinel wells, initially on a quarterly basis (unless and until modified by PADEP), is the only O&M requirement necessary.

PADEP has assumed the responsibility for assuring compliance with the institutional controls identified in the RODs for this Site, and the review of data generated as part of the 5-year review process. On April 16, 1997, PADEP and PennDOT entered into a Memorandum of Understanding (MOU). The MOU expresses the intent of PADEP and PennDOT that PennDOT will, *inter alia*, perform the sampling of the wells, water and sediment and implement institutional controls, as required by remedy selected in the 1996 ROD.

The statutorily required five-year review of the ground water treatment remedy selected in the 1987 ROD was completed on September 1996. Further five year reviews will be conducted pursuant to OSWER Directive 9355.7–02. ''Structure and Components of Five-Year Reviews,'' and/or other applicable guidance. The next scheduled five year review is set for September, 1998. Subsequent five year reviews will be conducted pursuant to the directive.

The remedies selected for this Site have been implemented in accordance with the three Records of Decision as modified and expanded in the EPA-approved Remedial Designs for the Operable Units and the 1992 ESD. Human health threats and potential environmental impacts have been reduced to acceptable levels. EPA and the PADEP find that the remedies implemented continue to provide adequate protection of human health and the environment.

EPA, with the concurrence of PADEP, believes that the criteria for deletion of this Site have been met. Therefore, EPA is proposing deletion of this Site from the NPL.

Dated: May 15, 1997.

W. Michael McCabe,

Regional Administrator, USEPA Region III.

[FR Doc. 97–13481 Filed 5–22–97; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

RIN 0991–AA91

Health Care Programs, Fraud and Abuse; Intent To Form the Negotiated Rulemaking Committee for the Shared Risk Exception

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

ACTION: Intent to form negotiated rulemaking committee and notice of meetings.

SUMMARY: We have been statutorily-mandated under section 216 of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, to establish a negotiated rulemaking committee in accordance with the Negotiated Rulemaking Act and the Federal Advisory Committee Act (FACA). The committee's purpose would be to negotiate the development of the interim final rule addressing the shared risk exception, in section 216 of HIPAA, to the Federal health care programs' anti-kickback provisions. The committee will consist of representatives of interests that are likely to be significantly affected by the interim rule. The committee will be assisted by an impartial facilitator. We are requesting public comments on whether we have properly identified interests that will be affected by key issues discussed below.

DATES: Comments will be considered if we receive them at the address provided below by no later than 5 p.m. on June 9, 1997.

The meetings will be held at 9:00 a.m. on June 17–18, 1997, and July 28–30, 1997.

ADDRESSES: Please mail or deliver your written comments (1 original and 3 copies) to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG–33–NOI, Room 5246, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code OIG–33–NOI. Comments received timely will be available for public inspections as they are received, generally beginning approximately 2 weeks after publication of a document, in Room 5550 of the Office of Inspector General at 330 Independence Avenue, S.W., Washington, D.C., on Monday through Friday of each week from 8:00 a.m. to 4:30 p.m., (202) 619–0335.

The meetings will be held at the Holiday Inn Capitol, 550 C Street, SW., Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Joel Schaer, (202) 619–0089, OIG Regulations Officer; Judy Ballard, (202) 690-7419, Convener.

SUPPLEMENTARY INFORMATION:

I. Negotiated Rulemaking Act

The Negotiated Rulemaking Act, Public Law 101–648 (5 U.S.C. 561–569), establishes a framework for the conduct of negotiated rulemaking and encourages agencies to use negotiated rulemaking to enhance the informal rulemaking process. Under the Act, the head of an agency must consider whether—

- There is a need for a rule;
- There are a limited number of identifiable interests that will be significantly affected by the rule;
- There is a reasonable likelihood that a committee can be convened with a balanced representation of person who (1) Can adequately represent the interests identified, and (2) are willing to negotiate in good faith to reach a consensus on the rulemaking;
- There is reasonable likelihood that a committee will reach a consensus on the rulemaking within a fixed period of time;
- The negotiated rulemaking process will not unreasonably delay the development and issuance of a final rule;
- The agency has adequate resources and is willing to commit such resources, including technical assistance, to the committee; and
- The agency, to the maximum extent possible consistent with the legal obligations of the agency, will use the consensus of the committee with respect to developing the rule proposed by the agency for notice and comment.

Negotiations are conducted by a committee chartered under the FACA (5 U.S.C. App. 2). The committee includes an agency representative and is assisted by an impartial facilitator. The goal of the committee is to reach consensus on the language or issues involved in a rule. If consensus is reached, it is used as the basis of the interim final rule. The process does not affect otherwise

procedural requirements of the FACA, the Administrative Procedure Act and other statutes.

II. Subject and Scope of the Rule

A. Need for the Rule

Section 216 of HIPAA (Public Law 104–191) mandates a negotiated rulemaking process for establishing standards for a statutory exception to the anti-kickback statute.

B. Subject and Scope of the Rule

The Federal health care programs' anti-kickback statute, set forth in section 1128B(b) of the Social Security Act (the Act), provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive bribes, kickbacks or other remuneration in order to induce business reimbursed by Medicare or other Federal health care programs. In addition, for violations of section 1128B(b), the Department has the authority to exclude a person or entity from participation in the Medicare or State health care programs, in accordance with section 1128(b)(7) of the Act.

Because the statutory language of the anti-kickback statute is quite broad, there was concern that many innocuous or even beneficial arrangements would be covered by the statute. As a result, section 14 of Public Law 100–93, the Medicare and Medicaid Patient and Program Protection Act of 1987, authorized the promulgation of regulations ''specifying payment practices that shall not be treated as a criminal offense under section 1128B(b) of the Social Security Act and shall not serve as the basis for an exclusion under section 1128(b)(7) of such Act.'' These have come to be known as the ''safe harbor'' regulations. To date, we have promulgated two final rules that have established 13 specific areas for ''safe harbor'' protection under the anti-kickback statute (July 21, 1991 (56 FR 35952) and January 25, 1996 (61 FR 2122)).

Section 216 of HIPAA specifically amends section 128B(b)(3)(F) of the Act to include a new statutory exception for risk-sharing arrangements. The provision establishes a new statutory exception from liability under the anti-kickback statute for remuneration between an eligible organization under section 1876 of the Act and an individual or entity providing items or services, or any combination thereof, in accordance with a written agreement between these parties. The provision also allows remuneration between an organization and an individual or entity if a written agreement places the individual or entity at ''substantial financial risk'' for the cost or utilization of the items or services provided. Section 216 requires the Department, in consultation with the Department of Justice, to engage in a negotiated rulemaking process to establish standards related to this exception for risk-sharing arrangements. The factors to be considered are (1) The level of risk appropriate to the size and type of arrangement; (2) the frequency of assessment and distribution of incentives; (3) the level of capital contribution; and (4) the extent to which the risk-sharing arrangement provides incentives to control the cost and quality of health care services.

C. Issues and Questions To Be Resolved

We anticipate some discussions about the basic approach to the rule, including what policy issues are properly considered in determining whether arrangements should be excepted from the anti-kickback provisions, whether flexibility or certainty in the rule is more important, and whether the definitions of terms used in the exception must be consistent with use of those terms in other contexts. In addition, we anticipate discussion on a limited number of specific issues.

Specific Issues for Discussion

The negotiated rulemaking will address the following specific issues.

- How is the term ''written agreement'' to be defined?

We expect discussion on whether the agreement should be of minimum duration, what the agreement should contain and whether unwritten side agreements should be prohibited.

- What does the term ''eligible organization under section 1876 of the Social Security Act'' mean?

We expect discussion on whether this phrase is limited to Medicare risk contractors (and to arrangements for services provided under Medicare contracts) or has a broader meaning. In addition, we expect discussions on whether the first part of the exception applies to remuneration only if it is in accordance with an agreement where an ''eligible organization'' is a party, or also if in accordance with ''lower level'' agreements, such as one between a physician and a physician group practice that has an agreement with a health maintenance organization. There may also be some discussion of the term ''organization'' as used in the second part of the exception.

- What is an ''individual or entity providing items or services or a combination thereof''?

We expect discussion on whether this includes entities such as drug companies or device manufacturers providing combinations of items and services, and when this constitutes ''bundling'' that would be harmful to the Federal health care programs without further protections. We also expect to address whether the services must be health care services or could be other services, such as marketing services.

- What constitutes ''substantial financial risk for the cost of utilization of items or service''?

The legislative history of the exception lists certain factors (such as the level of capital contribution) to be taken into account in determining whether the risk is substantial. We expect discussion on how these factors should be taken into account, what constitutes risk (for example, should bonuses and withholds be treated the same), and whether special treatment should be given to encourage providers to assume risk where they do not ordinarily do so or where risk is difficult to measure. In addition, we anticipate discussion about how to take into account the total risk-sharing arrangement between the parties.

Issues Outside the Scope of the Rule

With regard to parameters outside the scope of the rule, the OIG does not plan to negotiate the following issues—

- Whether any existing regulatory exceptions to the anti-kickback provisions (safe harbors) should be amended, or proposed safe harbors enacted;
- Whether any other new safe harbors should be enacted; or
- How the OIG should implement a requirement that it issue advisory opinions.

In addition, the OIG will not agree to adopt any practices or concepts that do not contain adequate controls on potential abuse or manipulation.

We invite public comment on issues not identified.

III. Affected Interests and Potential Participants

The convener has proposed, and we have agreed to accept, the following organizations as negotiation participants. We believe these organizations represent an appropriate mix of interests and backgrounds affected.

American Association of Health Plans
American Association of Retired Persons
American Health Care Association
American Hospital Association
American Medical Association

American Medical Group Association
Blue Cross Blue Shield Association
Consumer Coalition on Quality in Health Care
Coordinated Care Coalition
Department of Justice
Federation of American Health Systems
Health Industry Manufacturers Association
Heath Insurance Association of America
National Association of Community Health Centers
Independent Insurance Agents of America/National Association of Health Underwriters
National Association of Medicaid Fraud Control Units
National Association of State Medicaid Directors
Nation Rural Health Association
Pharmaceutical Research and Manufacturers Association
The IPA Association of America

The interests identified included law enforcement agencies, health programs, health plans, provider organizations, health care professionals and consumers. In determining whether the potential effect of the rule on provider and professional groups which sought to participate is ''significant,'' we considered the extent to which—

- Items or services provided by group members are covered by the relevant programs;
- Group members are entering into risk-sharing arrangements;
- The anti-kickback provisions have been applied to prosecute or prohibit arrangements which group members have used or considered using (either where one party is an ''eligible organization'' or where risk-sharing may be involved); and
- The group actively lobbied for the exception or commented on related provisions. We also sought to reflect differences in the type of risk that might be assumed and in the ways individuals or entities organize to provide items or services.

The intent in establishing the negotiating committee is that all interests are represented, not necessarily all parties. We believe this proposed list of participants represents all interests associated with the rule to be negotiated. We invite comment on this list of negotiation participants.

IV. Schedule for the Negotiation

We have set a deadline of 6 months beginning with the date of the first meeting for the committee to complete work on developing the interim final rule. We intend to terminate the activities of the committee if it does not appear likely to reach consensus within this time period.

The first meeting is schedule for June 17–18, 1997 at the Holiday Inn Capitol, 550 C Street, S.W., Washington, D.C. 20024. The first day's meeting will begin at 9:00 a.m. The purpose of this meeting will be discuss in detail how the negotiations will proceed and how the committee will function. The committee will—

- Agree to ground rules for committee operation;
- Hear presentations on the anti-kickback statute and related provisions, as well as what risk-sharing arrangements are being developed;
- Determine how best to address the principal issues; and
- If time permits, begin to address those issues.

A second meeting is scheduled for July 28–30, 1997 at the Holiday Inn Capitol, 550 C Street, S.W., Washington, D.C. 20024, beginning at 9:00 a.m. We expect that by this meeting the committee can complete action on any procedural matters outstanding from the organizational meeting, and either begin or continue to address the issues.

Subsequent meetings of the committee would be held approximately one month apart, in the Washington, D.C. area.

V. Formation of the Negotiating Committee

A. Procedure for Establishing an Advisory Committee

As a general rule, an agency of the Federal Government is required to comply with the requirements of FACA when it establishes or uses a group that includes nonfederal members as a source of advice. Under FACA, an advisory committee is established once the charter has been approved by the Secretary. We will not begin negotiations until the charter is approved.

B. Participants

The number of participants in the group should not exceed 25. A number larger than this could make it difficult to conduct effective negotations. One purpose of this notice to help determine whether the interim final rule would significantly affect interests not adequately represented by the proposed participants. We do not believe that each potentially affected organization or individual must necessarily have its own representative. However, each interest must be adequately represented. Moreover, we must be satisfied that the group as a whole reflects a proper balance and mix of interests.

C. Requests for Representation

If, in response to this notice, an additional individual or representative of an interest requests membership or representation in the negotiating group, we will determine, in consultation with the convener, whether that individual or representative should be added to the group. We will make that decision based on whether the individual or interest—

- Would be significantly affected by the rule; and
- Is already adequately represented in the negotiating group.

D. Establishing the Committee

After reviewing any comments on this notice and any requests for representation, we will take the final steps to form the committee.

VI. Negotiation Procedures

When the committee is formed, the following procedures and guidelines will apply, unless they are modified as a result of comments received on this notice or during the negotiating process.

A. Facilitator

We will use an impartial facilitator. The facilitator will not be involved with the substantive development or enforcement of the regulation. The facilitator's role is to—

- Chair negotiating sessions;
- Help the negotiation process run smoothly; and
- Help participants define and reach consensus.

B. Good Faith Negotiations

Participants must be willing to negotiate in good faith and be authorized to do so. We believe this must be accomplished by selection of senior officials as participants. We believe senior officials are best suited to represent the interests and viewpoint of their organizations. This applies to the OIG as well, and we are designating D. McCarty Thornton, Chief Counsel to the Inspector General, to represent the OIG.

C. Administrative Support

We will supply logistical, administrative and management support. If deemed necessary and appropriate, we will provide technical support to the committee in gathering and analyzing additional data or information.

D. Meetings

Meetings will be held at the Holiday Inn Capitol, 550 C Street, S.W., Washington, D.C. 20024 at the convenience of the committee. We are announcing the first two meetings through this notice, and will announce

committee meetings and agendas through further notices in the **Federal Register**. Unless announced otherwise, meetings are open to the public.

E. Committee Procedures

Under the general guidance and direction of the facilitator, and subject to any applicable legal requirements, the members will establish the detailed procedures for committee meetings that they consider most appropriate.

F. Defining Consensus

The goal of the negotiating process is consensus. Under the Negotiated Rulemaking Act, consensus means that each interest concurs in the result, unless the term is defined otherwise by the committee. We expect the participants to fashion their working definition of this term.

G. Failure of Advisory Committee To Reach Consensus

If the committee is unable to reach consensus, the OIG will proceed to develop an interim final rule. Parties to the negotiation may withdraw at any time. If this happens, the remaining committee members and the OIG will evaluate whether the committee should continue.

H. Record of Meetings

In accordance with FACA's requirements, minutes of all committee meetings will be kept. The minutes will be placed in the public rulemaking record.

I. Other Information

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

Dated: April 11, 1997.

June Gibbs Brown,

Inspector General.

Approved: May 19, 1997.

Donna E. Shalala,

Secretary.

[FR Doc. 97–13718 Filed 5–21–97; 10:02 am]

BILLING CODE 4150–04–M

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

49 CFR Part 1039

[STB Ex Parte No. 561]

Rail General Exemption Authority—Nonferrous Recyclables

AGENCY: Surface Transportation Board, DOT.

ACTION: Proposed rule; extension of comment due date.

SUMMARY: By decision served May 5, 1997, the Surface Transportation Board issued a notice of proposed rulemaking (NPR) proposing, *inter alia*, a total exemption from regulation for 29 nonferrous recyclable commodities. The NPR was not published in the **Federal Register** until May 16, 1997 (62 FR 27003) although parties in an earlier proceeding (Ex Parte No. 346 (Sub-No. 36)) were served with a copy of the May 5, 1997 NPR. The May 16 **Federal Register** publication provided for the filing of a notice of intent to participate on May 26, 1997, with comments due June 30, 1997, and reply comments due July 15, 1997. The Association of American Railroads (AAR), in a request dated May 8, 1997, and supplemented on May 14, 1997, has requested an extension of time to July 15, 1997, to file comments and to August 5, 1997, to file reply comments. AAR requests the extension to allow it and its members sufficient time to compile current information and to consult and coordinate a response among themselves and shippers of nonferrous recyclable commodities. AAR contacted three parties who had filed opposition comments in the earlier proceeding and reports that two of those parties do not object to the extension, and the third took no position. The extension request will be granted. Moreover, because the due date of May 26, 1997 for notice of intent is a federal holiday, that due date will be extended to May 27, 1997.

DATES: Persons interested in participating in this proceeding as a party of record by filing and receiving written comments must file a notice of intent to participate by May 27, 1997. Comments must be submitted by July 15, 1997, and reply comments are due August 5, 1997.

ADDRESSES: Send an original plus 10 copies of notices of intent to participate and pleadings referring to STB Ex Parte No. 561 to: Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, N.W., Washington, DC 20423–0001.

FOR FURTHER INFORMATION CONTACT: Beryl Gordon, (202) 565–1600. (TDD for the hearing impaired: (202) 565–1695.)

Decided: May 19, 1997.

By the Board, Vernon A. Williams, Secretary.

Vernon A. Williams,

Secretary.

[FR Doc. 97–13631 Filed 5–22–97; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 227 and 425

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Parts 17 and 425

Endangered and Threatened Species; Reopening of Comment Period on Proposed Threatened Status for a Distinct Population Segment of Anadromous Atlantic Salmon (Salmo salar) in Seven Rivers

AGENCIES: National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Commerce; and Fish and Wildlife Service, Interior.

ACTION: Reopening of public comment period.

SUMMARY: The State of Maine formally submitted the Maine Atlantic Salmon Conservation Plan (Plan) to the National Marine Fisheries Service and the U.S. Fish and Wildlife Service (collectively the Services) on March 5, 1997, in response to the Services' proposal to list Atlantic salmon in seven Maine rivers as threatened (60 FR 50530, September 29, 1995). The Services have determined that the Plan is significant new information relating to the proposed rule that merits review and consideration under the Endangered Species Act (ESA). The Services also note that information and data collected since the publication of the proposed rule is also available for review and has become part of the record for the Services' evaluation of the proposed listing. This information includes adult returns, redd counts, fry stocking, habitat assessments, commercial fishing agreements and management measures, and marine habitat assessment. Stocking, return and habitat data are provided in the Annual Report of the U.S. Atlantic Salmon Assessment Committee which is prepared annually for the U.S. Section to North Atlantic Salmon Conservation Organization. The annual field activity report prepared by the Maine Atlantic Salmon Authority and the U.S. Fish and Wildlife Service also documents management activities for the seven river populations. In order to ensure that the public has an opportunity to comment on all phases of this proposed listing, the Services are making the Plan available for review at selected locations throughout New England and the Washington DC area