42 CFR	OMB control Nos.
488.1–.28	0938–0355
488.4	0938–0690
488.18	0938–0667
488.26	0938–0379
488.60	0938–0360
489.20	0938–0667
489.21	0938–0357
489.24	0938–0667
489.27	0938–0692
489.40–.41	0938–0383
489.102	0938–0610
491.1–.11	0938–0074
491.2	0938–0685
491.9	0938–0334
493.1–.2001	0938–0151, 0170, 0544, 0581, 0612 & 0653
493.501, 493.506, 493.513, 493.515	0938–0686
493.1840	0938–0655
498.40–.95	0938–0486 & 0567
1003.100, 1003.101, 1003.103	0938–0700
1004.40, 1004.50, 1004.60, 1004.70	0938–0444

45 CFR	OMB control Nos.
146.111, .115, .117, .150, .152, .160, .180	0938–0702
148.120, .122, .124, .128	0938–0703

Dated: December 17, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Information Technology Investment Management Group; Division of HCFA Enterprise Standards.

[FR Doc. 97–33555 Filed 12–23–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Criteria for Implementing Permissive Exclusion Authority Under Section 1128(b)(7) of the Social Security Act

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

ACTION: Notice.

SUMMARY: This notice sets forth the non-binding guidelines, to be used by the OIG in assessing whether to impose a permissive exclusion in accordance with section 1128(b)(7) of the Social Security Act. These guidelines identify specific factors with regard to whether an individual's or entity's continued participation in the Medicare, Medicaid and other Federal health care programs will pose a risk to the programs or program beneficiaries, and explain how these factors would be used by the OIG to assess a permissive exclusion decision.

FOR FURTHER INFORMATION CONTACT: Joel Schaer, Office of Counsel to the Inspector General (202) 619–0089.

SUPPLEMENTARY INFORMATION:

I. Background

Purpose and Rationale

Section 1128(b)(7) of the Social Security Act (the Act) authorizes the Secretary, and by delegation the Inspector General, to exclude a provider from Medicare, Medicaid and the other Federal health care programs for engaging in conduct described in sections 1128A and 1128B of the Act. These latter provisions establish administrative and criminal sanctions, respectively, against individuals and entities that (1) submit, or cause to be submitted, false or fraudulent claims to Medicare and the Federal and State health care programs; or (2) offer, pay, solicit or receive remuneration in return for the referral of business reimbursed by Medicare or Medicaid, a violation of the Medicare and Medicaid anti-kickback statute. Exclusions in accordance with section 1128(b)(7) of the Act, based on such conduct, are permissive in nature, that is, the Secretary has the discretion whether to exclude or not to exclude. Respondents in these administrative exclusion proceedings have the right to a hearing before a Department of Health and Human Services administrative law judge prior to the imposition of an exclusion.

On October 24, 1997, the OIG published a proposed policy statement in the **Federal Register** (62 FR 55410) in the form of non-binding guidelines to be used by the OIG in assessing whether to impose a permissive exclusion in accordance with section 1128(b)(7) of the Act. We indicated that these draft criteria were designed to allow for the more effective development of OIG investigations and investigative plans; establish an objective basis for the OIG's permissive exclusion decisions; evaluate a provider's trustworthiness to continue to conduct business with the Medicare, Medicaid and other Federal health care programs; and positively influence providers' future behavior through the development of corporate integrity programs and other conduct contemplated by the exclusion criteria.

The factors listed in these proposed guidelines were derived from two principal sources—the regulations governing exclusions under sections 1128(b)(7) and 1128A of the Act (42 CFR parts 1001 and 1003), and the decisions of the Departmental Appeals Board (DAB) in exclusion matters. The factors derived from DAB decisions reflected the analysis of the remedial purpose of program exclusion that is, to protect Federal health care programs by determining whether the respondent is sufficiently trustworthy to participate.

Structure of Permissive Exclusion Criteria

The proposed exclusion criteria were organized into four general categories of factors bearing on the trustworthiness of a provider that has allegedly engaged in health care fraud and abuse—

- The first category addressed the circumstances and seriousness of the

underlying misconduct. The factors to be considered are historical in nature and rely on past misconduct as an indicator of the defendant's propensity for future abuse of the programs.

- The second category considered the defendant's response to the allegations or determination of wrongdoing. These factors indicate whether the defendant is willing to affirmately modify his or her conduct, make injured parties whole, and otherwise acknowledge and remedy past wrongdoing.
- The third category identified various other factors relevant to assessing the likelihood of a future violation of the law. The implementation of an adequate corporate integrity program is a key consideration.
- The fourth category related to the defendant's financial ability to provide quality health care services.

Interested parties were invited to comment on these draft criteria and submit their written comments to the OIG for consideration. The OIG received two timely-filed public comments in accordance with that solicitation request. As a result of those comments, we are making two technical revisions to the final guidelines. The first change relates to section D and the defendant's financial ability to provide quality health care services. We are clarifying this section to indicate its application only to entities and not individual practitioners. Second, we are revising the language in paragraph 3 of section A to address the ''knowledge standard.'' Specifically, we are now indicating that a criterion would be whether there is evidence that the defendant knew, or should have known, that his or her conduct was prohibited.

We believe that the revised internal guidelines set forth below should now establish specific criteria on which the OIG may base its decision as to whether to seek the imposition of a permissive exclusion against a health care provider in accordance with section 1128(b)(7) of the Act. While these revised exclusion criteria will now serve as internal agency guidelines for the OIG, these criteria may be subject to further modification at any time. They are not intended to limit or bind the OIG's discretionary authority to exclude individuals or entities that pose a risk to Medicare, Medicaid and other Federal health care programs or program beneficiaries. These criteria do not create any rights or privileges in favor of any party. In addition, these criteria do not supplant to modify in any way the OIG regulations, codified at 42 CFR part 1001, governing program exclusions.

II. Criteria To Implement the OIG's Permissive Exclusion Authority Under Section 1128(b)(7)

The following criteria may be used to determine whether or not it is appropriate to impose a permissive exclusion in accordance with section 1128(b)(7) of the Act (42 U.S.C. 1320a–7(b)(7)). These criteria are informal and non-binding, and may be used as a guide to assist the OIG in determining in which cases an exclusion should be imposed. The presence or absence of any or all of the factors that appear below does not constitute the sole grounds for determining whether exclusion is appropriate. There is a presumption that some period of exclusion should be imposed against an individual or entity that has defrauded Medicare or other Federal and State health care programs.

A. The Circumstances of the Misconduct and Seriousness of the Offense

1. Was a criminal sanction imposed? The amount of any criminal fine or penalty imposed, and the length of any period of incarceration that is ordered, is evidence of the seriousness of the statutory misconduct, and may have an impact on the exclusion determination.

2. Was there evidence of (i) physical or mental harm to patients or (ii) financial harm to the Medicare or any of the other Federal and State health care programs? If financial loss to the programs occurred, what was the extent of such loss? Exclusion may be appropriate not only in cases where actual harm is present, but potential harm as well.

3. Is the misconduct an isolated incident or a continuous pattern of wrongdoing over a significant period of time? Is there evidence that the defendant knew, or should have known, that his or her conduct was prohibited? Has the defendant had the same or previous problems with the OIG, the Health Care Financing Administration (HCFA), the carrier or intermediary, or the State? What was the nature of these problems?

4. Was the defendant's involvement in the misconduct active or passive? Was the defendant aware of the misconduct when it was occurring? Did the defendant play a role in the misconduct?

B. Defendant's Response to Allegations/ Determination of Unlawful Conduct

1. What was the defendant's response to any actual or potential legal violations or harm to the programs or their beneficiaries? Was the response appropriate and credible?

2. Did the defendant cooperate with investigators and prosecutors, and timely respond to lawful requests for documents and the provision of evidence regarding the involvement of other individuals in a particular scheme, thereby demonstrating trustworthiness?

3. Has the defendant made or agreed to make full restitution to the Federal and/or state health care programs, thereby demonstrating present responsibility and willingness to conform to applicable laws, regulations and program requirements?

4. Has the defendant paid or agreed to pay all criminal, civil, and administrative fines, penalties, and assessments resulting from the improper activity?

5. Has the defendant taken steps to undo the questionable conduct or mitigate the ill effects of the misconduct, e.g., appropriate disciplinary action against the individuals responsible for the activity that constitutes cause for exclusion, or other corrective action?

6. Has the defendant acknowledged its wrongdoing and changed its behavior, thereby demonstrating future trustworthiness?

C. Likelihood that Offense or Some Similar Abuse Will Occur Again

1. Was the misconduct the result of a unique circumstance not likely to recur? Is there minimal risk of repeat conduct?

2. Have prior and subsequent conduct been exemplary or improper?

3. What prior measures had been taken to ensure compliance with the law? Can the defendant demonstrate that it had an effective compliance plan in place when the activities that constitute cause for exclusion occurred?

A. Did the defendant make any efforts to contact the OIG, HCFA, or its contractors to determine whether its conduct complied with the law and applicable program requirements? Were any contacts documented?

B. Did the defendant bring the activity in question to the attention of the appropriate Government officials prior to any Government action, e.g., was there any voluntary disclosure regarding the alleged wrongful conduct?

C. Did the defendant have effective standards of conduct and internal control systems in place at the time of the wrongful activity, e.g., was there a corporate compliance program in place? If there was an existing corporate compliance plan:

(i) How long had the compliance plan been in effect?

(ii). What problems had been identified as a result of the compliance plan?

(iii). Were any overpayments or systemic changes made if problems were identified?

(iv) Were appropriate staff sufficiently trained in applicable policies and procedures pertaining to Medicare and other Federal and State health care programs?

(v) Was there a corporate compliance officer and an effective corporate compliance committee in place (if appropriate to the size of the company)?

(vi) Were regular audits undertaken at the time of the unlawful activity?

4. What measures have been taken, or will be taken, to ensure compliance with the law? Has the defendant agreed to implement adequate compliance measures, including institution of a corporate integrity plan?

D. Financial Responsibility

If the defendant is an entity and is permitted to continue program participation, is that defendant able to operate without a real threat of bankruptcy and without a real threat to its ability to provide quality health care items or services?

Dated: December 16, 1997.

June Gibbs Brown,

Inspector General.

[FR Doc. 97–33524 Filed 12–23–97; 8:45 am]

BILLING CODE 4150–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health (NIH)

National Institute on Aging; Notice of Meeting of the National Advisory Council on Aging

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the National Advisory Council on Aging, National Institute on Aging, Thursday, February 5, and Friday, February 6, 1998, to be held at the National Institutes of Health, Natcher Building, Conference Room F1 and 2, Bethesda, Maryland. This meeting will be open to the public on Thursday, February 5, from 1:00 to 4:30 p.m. for a status report by the Director, NIA, and the Behavioral and Social Research Program and Intramural Research Program Reviews.

The meeting will be open again on Friday, February 6, from 8:00 to 10:00 a.m. for a report on the Working Group on Program, a report on the Council Task Force on Minority Aging and Highlights of Recent Research Findings. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and sec. 10(d) of Pub. L. 92–463, the meeting of the Council will be closed to the public on Thursday, February 5, from 4:30 p.m. to recess for the review of the Intramural Research Program.

The meeting will also be closed on Friday, February 6, from 10:00 a.m. to adjournment for the discussion and evaluation of grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as a patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. June McCann, Committee Management Officer for the National Institute on Aging, National Institutes of Health, Gateway Building, 7201 Wisconsin Avenue, Suite 2C218, Bethesda, Maryland 20892 (301/496–9322), will provide a summary of the meeting and a roster of committee members upon request.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. McCann at (301) 496–9322, in advance of the meeting.

(Catalog of Federal Domestic Assistance Program No. 93.866, Aging Research, National Institutes of Health)

Dated: December 17, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–33490 Filed 12–23–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of Environmental Health Sciences Special Emphasis Panel (SEP) meeting:

Name of SEP: Review of Conference Grants (R13s) and Conference Cooperative Agreements (U13s) Telephone Conference Call.

Date: January 9, 1998.

Time: 2:30 p.m.

Place: National Institute of Environmental Health Sciences, North Campus, Building 4401, Room 3446, Research Triangle Park, NC 27709.

Contact Person: Dr. Carol Shreffler, National Institute of Environmental Health Sciences, P.O. Box 12233, Research Triangle Park, NC 27709, (919) 541–1445.

Purpose/Agenda: To review and evaluate grant applications.

This meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Grant applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Programs Nos. 93.113, Biological Response to Environmental Agents; 93.114, Applied Toxicological Research and Testing; 93.115, Biometry and Risk Estimation; 93.894, Resource and Manpower Development, National Institutes of Health)

Dated: December 17, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–33491 Filed 12–23–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Meeting: Allergy, Immunology, and Transportation Research Committee

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the Allergy, Immunology, and Transplantation Research Committee on February 10–12, 1998, at the Belmont Manor House and Conference Center, 6555 Belmont Woods Road, Elkridge, Maryland.

The meeting will be open to the public from 8:30 a.m. to 9:30 a.m. on February 10 to discuss administrative details relating to committee business and program review, and for a report from the Acting Director, Division of Extramural Activities, which will include a discussion of budgetary matters. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and sec. 10(d) of Pub. L. 92–463, the meeting will be closed to the public for the review, discussion, and evaluation of individual grant applications and contract proposals from 9:30 a.m. on February 10 until