DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Grassroots Regulatory Partnership Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) (Office of Regulatory Affairs, Nashville District Office and New Orleans District Office), in conjunction with the Health Industry Manufacturers Association (HIMA) is announcing the following workshop: Grassroots Regulatory Partnership Workshop. The topic to be discussed is FDA regulatory requirements for the medical device industry. The purpose of the workshop is to promote open dialogue between FDA and the medical device industry on quality system regulations and medical device reporting requirements.

Date and Time: The workshop will be held on Tuesday, December 16, 1997, from 8:30 a.m. to 5 p.m, and on Wednesday, December 17, 1997, from 8 a.m. to 3 p.m.

Location: The meeting will be held at the Holiday Inn Select–Vanderbilt, 2613 West End Ave., Nashville, TN 37203, 1–800–633–4427.

Contact: Rebecca K. Keenan, Food and Drug Administration (HFR–SE–350), Nashville District Office, 297 Plus Park Blvd., Nashville, TN 37217, 615–781–5380, ext. 145, FAX 615–781–5391.

Registration: Fax registration information (including name, title, firm name, address, telephone, and fax number) to the contact person by November 20, 1997. There is no registration fee for this workshop. Space is limited, therefore interested parties are encouraged to register early.

If you need special accommodations due to a disability, please contact Rebecca K. Keenan at least 7 days in advance.

SUPPLEMENTARY INFORMATION: In 1995 President Clinton directed the heads of all Federal regulatory agencies to carry out a four step regulatory reinvention initiative. The basic idea of the President's initiative was to replace adversarial approaches with a partnership approach based on clear goals and cooperation. The President specifically directed top management from regulatory agencies to hold ''grassroots'' workshops with regulated industry, and this workshop is designed to meet that requirement.

Priority will be given to those businesses located in the Nashville and New Orleans Districts, which include the States of: Alabama, Louisiana, Mississippi, and Tennessee. Companies located outside of these States may register to attend the workshop and will be accepted if space is available.

Dated: October 17, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–28170 Filed 10–23–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1513]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Reinstatement, with change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Medicare/Medicaid Disclosure of Ownership and Control Interest Statement and Supporting Regulations in 42 CFR 420.200–.206, 455.100–.106; *Form No.:* HCFA–1513 (OMB# 0938–0086); *Use:* The Medicare/Medicaid Disclosure of Ownership and Control Interest Statement must be used by State agencies and HCFA regional offices to determine whether providers meet the eligibility requirements for Titles 18 and 19 (Medicare and Medicaid) and for grants under Titles V and XX. Review of ownership and control is particularly necessary to prohibit ownership and control for individuals excluded under Federal fraud statutes; *Frequency:* Other (every 1 to 3 years); *Affected Public:* Business or other for-profit, and Not-for-profit institutions; *Number of Respondents:* 92,000; *Total Annual Responses:* 92,000; *Total Annual Hours:* 46,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: October 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. 97–28208 Filed 10–23–97; 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 a proposed policy statement, 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 Social Security Act. These guidelines identify specific factors with regard to whether an individual's or entity's continued participation in the Medicare and other Federal and State 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.

COMMENT PERIOD: Parties interested in commenting on these guidelines may submit their written comments to the

address provided below by no later than 5 p.m. on November 24, 1997. Comments will be available for public inspection beginning on [14 days after date of publication in the **Federal Register**] in Room 5518 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) 619–0089.

ADDRESSES: Please mail or deliver any written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG–821–N, Room 5246, Cohen Building 330 Independence Avenue, S.W., Washington, D.C. 20201.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code OIG–821–N.

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

SUPPLEMENTARY INFORMATION:

I. Background

Purpose and Rationale

Internal guidelines have been developed by the OIG to provide specific criteria on which it will 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 Social Security Act (the Act).

Section 1128(b)(7) of the Act authorizes the Secretary, and by delegation the Inspector General, to exclude a provider from Medicare and the other Federal and State health care programs for engaging in conduct described in sections 1128A and 1128B of the Act. These 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. 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.

We believe these criteria will serve a number of useful purposes by (1) allowing for the more effective development of OIG investigations and investigative plans; (2) establishing an objective basis for the OIG's permissive exclusion decisions, and evaluating a provider's trustworthiness to continue to conduct business with the Medicare and other Federal and State health care programs; and (3) positively influencing providers' future behavior through the development of corporate integrity programs and other conduct contemplated by the exclusion criteria.

Structure of Permissive Exclusion Criteria

The exclusion criteria are 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 addresses 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 considers the defendant's response to the allegations or determination of wrongdoing. These factors indicate whether the defendant is willing to affirmatively modify his or her conduct, make injured parties whole, and otherwise acknowledge and remedy past wrongdoing.
- The third category identifies 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 relates to the defendant's financial ability to provide quality health care services.

These exclusion criteria will merely serve as internal agency guidelines that may be subject to further modification at any time. They are not intended to limit the OIG's discretionary authority to exclude individuals or entities that pose a risk to Medicare and other Federal and State health care programs or program beneficiaries, nor do they create any rights or privileges in favor of any party. Further, these criteria do not supplant or modify in any way the OIG regulations, codified at 42 CFR part 1001, governing program exclusions.

The factors listed in the guidelines are derived from two principle 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 reflect the analysis of the remedial purpose of program exclusion.

II. Proposed 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 favorable presumption that a 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 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 change 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 permitted to continue program participation, is the 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: October 14, 1997.

June Gibbs Brown,

Inspector General.

[FR Doc. 97–28202 Filed 10–23–97; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 Cancer Institute Special Emphasis Panel (SEP) meeting.

Name of SEP: Community Clinical Oncology Program.

Date: November 17–18, 1997.

Time: 8:30 a.m. to Adjournment.

Place: Key Bridge Marriott, 1401 Lee Highway, Arlington, VA 22209.

Contact Person: Ray Bramhall, Ph.D., Scientific Review Administrator, National Cancer Institute, NIH, Executive Plaza North, Room 636B, 6130 Executive Boulevard, MSC 74, Bethesda, MD 20892–7407; Telephone: 301/496–3428.

Purpose/Agenda: To review, discuss and evaluate grant applications.

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

(**Catalog of Federal Domestic Assistance Program Numbers:** 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control)

Dated: October 17, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, National Institutes of Health.

[FR Doc. 97–28183 Filed 10–23–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 meeting of the National Cancer Institute Initial Review Group:

Agenda/Purpose: To review, discuss and evaluate grant applications.

Committee Name: Subcommittee G—Education.

Date: November 18–19, 1997.

Time: 8 a.m. to Adjournment.

Place: Holiday Inn—Georgetown, 2101 Wisconsin Avenue, NW., Washington, DC 20007.

Contact Person: Susan B. Spring, Ph.D., Scientific Review Administrator, National Cancer Institute, NIH, 6130 Executive Blvd., EPN, Room 643C, Bethesda, Md 20892–7403; Telephone: 301–402–0996.

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

(**Catalog of Federal Domestic Assistance Program Numbers:** 93,393, Cancer Cause and Prevention Research, 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control)