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 affirmatively 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?

4. Has the defendant made 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. 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 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 to the attention of the appropriate Government officials prior to any Government action, e.g., were there any voluntary disclosures 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 plan in place? If there was an existing corporate compliance plan:

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

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.