filed, the witness (and his or her attorney), upon proper identification, shall have the right to inspect the official transcript of the witness' own testimony. If such a petition is denied by the General Counsel, he shall inform the petitioner of the right to inspect the transcript.

(c) Good cause for denying a witness' petition to procure a transcript of his or her testimony may include, but shall not be limited to, the protection of: trade secrets and confidential business information contained in the testimony, security-sensitive operational and vulnerability information, and the integrity of Board investigations.

Dated: December 2, 2002.

Christopher W. Warner,
General Counsel.

[FR Doc. 02–3989 Filed 12–6–02; 8:45 am]
Medicaid beneficiaries. In the absence of statutory guidance, attempting to distinguish among types of benefits or categories of beneficiaries necessarily results in arbitrary standards. In these circumstances, the OIG has determined to exercise its regulatory authority cautiously by limiting exceptions to areas in which Congress has indicated a desire for flexibility in the provision remuneration to beneficiaries or where the provision of such remuneration serves a governmental interest.

B. Specific Areas of Interest

1. Complimentary Local Transportation

In enacting section 1128A(a)(5) of the Act, Congress intended that the statute not preclude the provision of complimentary local transportation of nominal value (H.R. Conf. Rep. No. 104-191 at 255 (1996)). We have interpreted nominal value to mean no more than $10 per item or service or $50 in the aggregate. (See 65 FR 24411; April 6, 2000.) We are concerned that this interpretation may be overly restrictive in the context of complimentary local transportation. According to the Office of Inspector General (OIG), public input on the following issues as they relate to a possible exception for complimentary transportation:

- **Forms of transportation.** What forms of transportation should be considered in developing an exception and how should various forms of transportation be treated? We believe that luxury transportation (e.g., limousines), as well as certain specialized transportation (e.g., ambulances) should not be covered in an exception. Are there other forms of transportation that should be excluded (e.g., handicapped-accessible vans, taxis, public transportation)?
- **Area in which transportation is offered.** Should the complimentary transportation service be limited to a provider’s primary service area? If so, how should a service area be defined? Should there be a different rule for rural or underserved areas or patients? Should complimentary transportation be permitted to the nearest facility even if the patient resides outside the primary service area?
- **Eligibility for transportation.** Should providers be required to offer the transportation services to all patients? What other kinds of eligibility requirements might be permitted? Certain eligibility criteria, such as diagnosis or insurance coverage, would clearly raise significant issues. What about other eligibility criteria, such as a showing of transportation or financial need, chronic conditions, special services, or safety or treatment compliance?
- **Type of provider offering the transportation.** Should the rules be different depending on the type of provider or supplier offering the transportation services? Free transportation services offered by individuals or small groups of providers, including physicians, or by freestanding clinics have been subject to greater scrutiny. Historically, for example, unscrupulous providers and clinics have offered free transportation in conjunction with Medicare and Medicaid frauds.
- **Destination.** Should a provider be permitted to furnish transportation to other health care providers or only to its own premises for appointments for its own services? Some hospitals apparently provide free transportation to patients for private office visits with local physicians or other professionals; others limit transportation service to practitioners with hospital staff privileges. In addition, many hospitals and physician practices are co-located on a single campus. What safeguards might be included to protect against abuse if transportation is offered to the premises of other providers (e.g., free transportation of patients as a financial benefit to other providers)? What about transportation among entities affiliated through health systems? What about transportation for reasons other than medical appointments?
- **Marketing and advertising.** What are the practical and policy considerations associated with allowing marketing or advertising of complimentary transportation services? What would constitute reasonable limits on promotional activities?
- **Other criteria.** Are there other safeguards, limitations, or conditions that should apply in any exception for complimentary transportation?

2. Clinical Trials

Historically, sponsors of clinical trials have offered various inducements to patients to enroll in their trials. Because Medicare did not cover medical services incident to most clinical trials, these inducements did not trigger scrutiny under the various federal program fraud and abuse sanctions. However, in 2000, the Centers for Medicare and Medicaid Services (CMS) issued a national coverage determination (NCD) providing for coverage for physician, hospital, and other services incidental to certain clinical trials (“Medicare Coverage Routine Costs of Beneficiaries in Clinical Trials” for September 19, 2000). Under the NCD, all other requirements of the Medicare program apply, including the various fraud and abuse authorities. In extending coverage to certain clinical trials, CMS intended to remove impediments to Medicare beneficiaries who want to enroll in trials, but not to grant favored status to clinical trials. This distinction is important, because many clinical trials involve unproven alternatives to existing effective treatments.

Because we are concerned that section 1128A(a)(5) not unduly impede valuable clinical trials, we are soliciting comments and suggestions on how to apply section 1128A(a)(5) to inducements to participate in bona fide clinical trials. Issues of particular interest to the OIG include:

- **Threshold level of Medicare reimbursement.** In many clinical trials, the volume and value of covered Medicare services provided to enrollees is likely to be significant, and trial sponsors may have a financial incentive to offer inducements to Medicare beneficiaries to enroll. For example, hospitalization triggers a substantial Medicare payment. However, it is possible that some clinical trials may involve only a small volume or value of Medicare covered services. Should a possible exception turn on the volume or value of Medicare services involved? If so, what would be the appropriate threshold level?
- **Sponsorship of studies.** One issue in crafting an exception for inducements associated with clinical trials would be defining the universe of trials that would be covered by the exception. We believe covered trials should have a clear potential public benefit. The scope of “deemed” trials under the NCD is overly broad for purposes of a possible exception to section 1128A(a)(5) of the Act. We are interested in comments regarding the scope of covered trials and the criteria that might apply to distinguish those with potential public benefit from those with solely or chiefly commercial value. We are also concerned that, as noted in several OIG studies, some trial sponsors provide investigators and other persons in positions to identify and influence potential enrollees with substantial monetary payments. (See, for example, the OIG report issued in June 2000, entitled “Recruiting Human Subjects: Pressures in Industry-Sponsored Clinical Research” (OEI-01–97–00195)).
- **Type or amount of inducements.** We are interested in information regarding the types of beneficiary inducements that might be offered in connection with clinical trials (e.g., transportation of otherwise uncovered services, drugs, or equipment). In the clinical trial context,
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: Notice of intent to develop regulations.

SUMMARY: In accordance with section 205 of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, this annual notice solicits proposals and recommendations for developing new and modifying existing safe harbor provisions under the anti-kickback statute (section 1128B(b) of the Social Security Act), as well as developing new OIG Special Fraud Alerts. In addition, this notice solicits public comments regarding the development of possible guidance addressing certain credentialing practices.

DATES: To assure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on February 7, 2003.

ADDRESSES: Please mail or deliver your written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG–71–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–71–N. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 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 Schaefer, (202) 619–0099, 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 or reward business reimbursable under the Federal 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 propose the imposition of civil money penalties, in accordance with section 1128A(a)(7) of the Act (42 U.S.C. 1320a–7a), or exclusions from the Federal health care programs, in accordance with section 1128(b)(7) of the Act (42 U.S.C. 1320a–7(b)(7)).

Since the statute on its face is so broad, concern has been expressed for many years that some relatively innocuous commercial arrangements may be subject to criminal prosecution or administrative sanction. In 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, specifying various payment and business practices which, although potentially capable of inducing referrals of business reimbursable under the Federal health care programs, would not be treated as criminal offenses under the anti-kickback statute and would not serve as a basis for administrative sanctions. 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 related administrative authorities. The safe harbor provisions are codified at 42 CFR 1001.952.

B. OIG Special Fraud Alerts and Special Advisory Bulletins

The OIG has also periodically issued Special Fraud Alerts and Special Advisory Bulletins to give continuing guidance to health care providers with respect to practices the OIG finds potentially fraudulent or abusive. The Special Fraud Alerts and Bulletins encourage industry compliance by giving providers guidance that can be applied to their own businesses. The OIG Special Fraud Alerts and Bulletins are intended for extensive distribution directly to the health care provider community, as well as those charged with administering the Federal health care programs. The OIG Special Fraud Alerts and Bulletins are available on the...