

open or leaking drums remained on the property.

In 1986, EPA removed and disposed of open drums, liquids, and other immediate threats. The site was proposed for inclusion on the National Priorities List in May 1988 and finalized in March 1989. EPA then initiated an RI/FS to determine the nature and extent of contamination at the Industrial Latex site, and to develop and evaluate alternatives to address the contamination.

Based on the RI/FS and after receiving public input, EPA issued a ROD in September 1992, which outlined the cleanup plan for the site. The plan included: (1) Excavation of contaminated soil and on-site treatment by low temperature thermal desorption, followed by backfilling on the site; (2) excavation and off-site disposal of buried drums; (3) dismantling and off-site disposal of vats; and (4) demolition and off-site disposal of two buildings on the site.

On April 10, 1996, EPA issued an Explanation of Significant Differences changing or eliminating a number of remediation goals specified in the ROD. These changes were based on sampling conducted after the ROD was signed. The four remaining site-related contaminants of concern at the Industrial Latex site were PCBs, bis(2-ethylhexyl)phthalate, 3,3'-dichlorobenzidine, and arsenic.

Because the results of the ground water investigation were inconclusive, the 1992 ROD called for a subsequent investigation. This investigation was completed in August 2001 and a ROD was signed on September 27, 2001. The ROD selected a no action remedy for ground water at the site. No action was needed because the ground water at the site poses no unacceptable risk to human health or the environment.

The cleanup of the site was accomplished in two phases. The first phase, involving the demolition of the buildings and removal of the vats, started in July 1995 and was completed in November 1995. Field work for the second phase, addressing the soil and buried drums, began in December 1998 and was completed in August 2000.

During the soil remediation, approximately 53,600 cubic yards of material were excavated, treated on-site via low temperature thermal desorption, and then backfilled on the site.

The site has been cleaned up to an unrestricted, residential use standard. All activities at the Industrial Latex site are complete and the site poses no unacceptable risk to human health or the environment. Therefore, no operation and maintenance activities or

institutional controls are required at the site. A five-year review of the remedy is also not required.

Public participation activities for the Industrial Latex site have been satisfied as required in CERCLA section 113(k), 42 U.S.C. 9613(k), and section 117, 42 U.S.C. 9617. The RI/FS, the RODs and the ESD were subject to a public review process. All other documents and information which EPA relied on or considered in recommending that no further activities are necessary at the Industrial Latex site, and that the site can be deleted from the NPL, are available for the public to review at the information repositories.

One of the three criteria for site deletion specifies that EPA may delete a site from the NPL if "all appropriate Fund-financed response under CERCLA has been implemented, and no further response action by responsible parties is appropriate." 40 CFR 300.425(e)(1)(ii). EPA, with the concurrence of the State of New Jersey, through the New Jersey Department of Environmental Protection, believes that this criterion for deletion has been met. Subsequently, EPA is proposing deletion of this site from the NPL.

In a letter dated August 29, 2002, the New Jersey Department of Environmental Protection concurred with EPA.

List of Subjects in 40 CFR Part 300

Environmental protection, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: September 17, 2002.

Jane M. Kenny,

Regional Administrator—Region II.

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CHEMICAL SAFETY AND HAZARD INVESTIGATION BOARD

40 CFR Part 1610

Transcripts of Witness Testimony in Investigations

AGENCY: Chemical Safety and Hazard Investigation Board.

ACTION: Proposed rule.

SUMMARY: The Chemical Safety and Hazard Investigation Board ("CSB" or "Board") proposes a new rule concerning transcripts of the testimony of witnesses appearing at Board depositions. The proposed rule provides that witnesses have the right to petition

to procure a copy of a transcript of their testimony, except that due to the nonpublic nature of Board depositions, witnesses (and their counsel) may for good cause be limited to inspection of the official transcript of their testimony.

DATES: Submit comments on or before January 8, 2003.

ADDRESSES: Address all comments concerning this proposed rule to Raymond C. Porfiri, Chemical Safety and Hazard Investigation Board, 2175 K Street, NW., Suite C-100, Washington, DC 20037.

FOR FURTHER INFORMATION CONTACT: Raymond C. Porfiri, 202-261-7600.

SUPPLEMENTARY INFORMATION: The Chemical Safety and Hazard Investigation Board is mandated by law to "investigate (or cause to be investigated), determine and report to the public in writing the facts, conditions, and circumstances and the cause or probable cause of any accidental release [within its jurisdiction] resulting in a fatality, serious injury or substantial property damages." 42 U.S.C. 7412(r)(6)(C)(i). The Board has developed practices and procedures for conducting investigations under this provision in 40 CFR 1610 and has spelled out the rights of witnesses to be represented in such proceedings (section 1610.1) and rules concerning attorney misconduct, (section 1610.2) and sequestration of witnesses and exclusion of counsel (section 1610.3). The Board has determined that it would be useful to add a provision concerning the taking, handling, and inspection of transcripts of Board depositions.

In proposing this regulation, the Board is following section 555(c) of the Administrative Procedure Act, which provides:

A person compelled to submit data or evidence is entitled to retain or, on payment of lawfully prescribed costs, procure a copy or transcript thereof, except that in a nonpublic investigatory proceeding the witness may for good cause be limited to inspection of the official transcript of his testimony.

On its face, section 555(c) recognizes that it is sometimes necessary to balance a compelled witness' right to have access to his or her testimony, and an agency's need to limit the dissemination of sensitive matters revealed in such testimony.

Board depositions are nonpublic investigatory proceedings. Attendance at depositions is limited to the minimum number of necessary CSB staff, the witness, and one attorney representing the witness. Depositions are not open to multiple attorneys

representing the witness, non-attorney representative of the witness, or representatives of other parties (40 CFR part 1610). The Board's regulations on Freedom of Information Act requests (40 CFR part 1601) and on Production of Records in Legal Proceedings (40 CFR part 1612) further demonstrate that the Board recognizes that some of the information obtained in its investigation may not be appropriate for public dissemination.

Several considerations have led the Board to conclude that it is necessary to establish a mechanism to ensure appropriate control over the dissemination of deposition transcripts while also respecting witness' rights under the Administrative Procedure Act. Because of the nature of Board investigations, deposition testimony may contain sensitive information. For example, testimony may reveal trade secrets and confidential business information, which are protected by the Trade Secrets Act, 18 U.S.C. 1905.

Protection of the integrity of Board investigations also necessitates control over the dissemination of deposition transcripts. First-hand witness accounts are an invaluable source of information about the events leading to, and causes of, chemical incidents. Witnesses can be reluctant to cooperate, though, out of fear of whistleblower retaliation. The CSB would likely have greater difficulty obtaining vital testimony if witnesses believed that their testimony could easily become known to their employers and to other witnesses. Reasonable limits, such as proposed in this regulation, on the dissemination of transcripts also helps to prevent the coaching of future witnesses based on testimony already given. Such preparation is undesirable in health and safety investigations, where it is important to gather unvarnished facts and untainted recollections.

Ultimately, the Board's duty is to obtain the facts about chemical incidents and to report objectively based on those facts. The Administrative Procedure Act provision limiting the release of transcripts in non-public proceedings is intended to facilitate missions such as the Board's. It protects against harms that would be caused by premature circulation of such transcripts, while protecting the witness' rights by allowing him or her to inspect the official transcript. This approach, embodied in this proposed regulation, is also consistent with the principles of Attorney General Ashcroft's October 12, 2001, "Memorandum for Heads of All Federal Departments and Agencies," on the Freedom of Information Act, in which

he said, "Any discretionary decision by your agency to disclose information protected under the FOIA should be made only after full and deliberate consideration of the institutional, commercial, and personal privacy interests that could be implicated by disclosure of the information."

This proposal is modeled on the rules of the Securities and Exchange Commission (17 CFR 203.6) and those of other agencies which also follow the APA and permit the agency to limit witnesses to inspection of transcripts in non-public investigatory proceedings for good cause. The Board has followed the APA process by allowing witnesses, after their testimony, to ask the General Counsel for the opportunity to procure a copy of the transcript, provided, of course, that for good cause, the General Counsel may deny the petition and limit the witness (and his or her counsel) to an inspection of the witness' testimony. This proposed regulation also makes it clear that this right to inspect the transcript is a right guaranteed by the APA and that witnesses who seek copies of the transcript are informed by the General Counsel of their right to inspect it.

As the court stated in *SEC v. Sprecher*, 594 F.2d 317, 319 (2d Cir 1979), "[I]t is obviously impractical for the Commission to determine prior to the testimony of a witness whether there will be 'good cause' to withhold a copy of the testimony from that witness, and we do not read the APA as requiring such an advance determination."

Moreover, the courts have made it clear that the APA "does not require [the agency] to spell out the 'good cause' which was the basis for the refusal to sell copies of the transcript." *Commercial Capital Corp. v. SEC*, 360 F.2d 856, 858 (7th Cir. 1966).

In summary, this regulation largely tracks the language of the APA. The courts have recognized that such regulations are properly designed to "permit the [agency] to enjoy confidentiality, where it is necessary, in order effectively to complete its investigation." *Zients v. La Morte*, 319 F. Supp 956, 958 (S.D.N.Y. 1970) (discussing purpose of the SEC regulation), accord *Lamorte v. Mansfield*, 438 F.2d 448 (2d Cir 1971), (Friendly, J.) ("to the extent that a privilege exists, it is the agency's not the witness's").

Regulatory Flexibility Act

The Board, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 605(b), has reviewed this proposed regulation and certifies that it will not

have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This proposed rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995, Public Law 104-4, 109 Stat. 48.

Federalism (E.O. 13132)

The CSB has determined this proposed regulation conforms to the federalism principals of Executive Order 13132. It also certifies that to the extent a regulatory preemption occurs, it is because the exercise of state and tribal authority conflicts with the exercise of federal authority under the U.S. Constitution's supremacy clause and federal statute.

Paperwork Reduction Act

This proposed regulation contains no reporting or recordkeeping requirements which require approval by the Office of Management and Budget under 44 U.S.C. 3510 *et seq.*

List of Subjects in 40 CFR Part 1610

Administrative practice and procedure, Investigations.

For the reasons set forth in the preamble, the Chemical Safety and Hazard Investigation Board proposes to amend 40 CFR part 1610 as follows:

PART 1610—ADMINISTRATIVE INVESTIGATIONS

1. The authority citation for part 1610 is revised to read as follows:

Authority: 42 U.S.C. 7412(r)(6)(C)(i), 7412(r)(6)(L), 7412(r)(6)(N).

Section 1610.4 also issued under 5 U.S.C. 555.

2. Add § 1610.4 to read as follows:

§ 1610.4 Deposition Transcripts.

(a) Transcripts of depositions of witnesses compelled by subpoena to appear during a Board investigation, shall be recorded solely by an official reporter designated by the person conducting the deposition.

(b) Such a witness, after completing the compelled testimony, may file a petition with the Board's General Counsel to procure a copy of the official transcript of such testimony. The General Counsel shall rule on the petition, and may deny it for good cause. Whether or not such a petition is

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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

Solicitation of Public Comments on Exceptions Under Section 1128A(a)(5) of the Social Security Act

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

ACTION: Notice of intent to develop regulations.

SUMMARY: The OIG is soliciting public comments on the possible development of exceptions under section 1128A(a)(5) of the Social Security Act (the Act), the civil money penalty (CMP) prohibition on offering inducements to Medicare and Medicaid beneficiaries to influence their selection of a provider, practitioner, or supplier. In particular, the OIG is interested in comments on possible exceptions for complimentary local transportation, inducements related to clinical trials, and inducements of nominal value. The OIG welcomes suggestions for other exceptions under section 1128A(a)(5) of the Act, as well.

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-72-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-72-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 Schaer, (202) 619-0089, OIG Regulations Officer

SUPPLEMENTARY INFORMATION:

I. Background

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, amended the Social Security Act (the Act) to prohibit providers from offering patients any inducement to order or receive Medicare or Medicaid reimbursable items or services from a particular provider, practitioner, or supplier. Specifically, section 231(h) of HIPAA established a new provision, section 1128A(a)(5) of the Act, to provide for the imposition of a CMP against any person who:

Offers or transfers remuneration to any individual eligible for benefits under [Medicare or Medicaid] that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under [Medicare or Medicaid].

Section 231(h) of HIPAA also created a new section 1128A(i)(6) of the Act to define "remuneration" for purposes of section 1128A(a)(5) of the Act. This section defines "remuneration," in relevant part, as "transfers of items or services for free or for other than fair market value." Remuneration does not include certain enumerated practices, including waivers of coinsurance and deductible amounts if the waiver is not advertised; not routinely offered; and made following an individualized good faith assessment of financial need or after the failure of reasonable collection efforts. Other statutory exceptions include properly disclosed copayment differentials in health plans; incentives to promote the delivery of preventive health care services; any practice permitted under a safe harbor to the federal anti-kickback statute at 42 CFR 1001.952; and waivers of hospital outpatient copayment amounts in excess of the minimum copayment amounts.

In 1998, Congress enacted section 6201 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act for Fiscal Year 1999, which authorized the Secretary to issue regulations establishing "safe harbor" exceptions under section 1128A(a)(5) of the Act for payment practices that would otherwise run afoul of the statute. In addition, the Secretary is vested with the authority to issue advisory opinions providing legal and regulatory guidance to providers under this section.

The OIG issued proposed regulations interpreting section 1128A(a)(5) of the Act on March 25, 1998 (63 FR 14393) and final regulations on April 26, 2000 (65 FR 24400). To alert the industry to the scope of acceptable practices, promote compliance, and level the competitive playing field, we have issued further guidance on the statute in a Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries (67 FR 55855; August 30, 2002). In the Bulletin, we indicated our intent to solicit public comments on the possible regulatory exceptions to the statute.

II. Solicitation of Comments and Suggestions for Additional Exceptions

The OIG invites comments and suggestions for new regulatory exceptions to section 1128A(a)(5) of the Act. In particular, we are seeking comments and suggestions on possible exceptions for complimentary local transportation; remuneration to induce participation in clinical trials; and inducements of low value. We also welcome comments on other possible exceptions to section 1128A(a)(5). Comments that include detailed descriptions of relevant industry business practices, address the legal and policy concerns raised by the application of section 1128A(a)(5) to particular business practices, and offer specific suggestions for applicable criteria that might apply under a regulatory exception are particularly useful.

A. Criteria for Establishing Exceptions

In giving the OIG authority to create additional regulatory exceptions to—and issue advisory opinions on—section 1128A(a)(5) of the Act, Congress provided no guidance on the criteria to be applied. The absence of criteria is especially problematic because any exception to the prohibition creates the very harm prohibited (*i.e.*, the inducement of beneficiaries), resulting in an uneven competitive playing field. Moreover, any exception will result in a valuable benefit to Medicare and