

FEDERAL TRADE COMMISSION**Children's Online Privacy Protection Safe Harbor Proposed Self-Regulatory Guidelines; Children's Advertising Review Unit of the Council of Better Business Bureaus, Inc.**

AGENCY: Federal Trade Commission.

ACTION: Notice of proposed "safe harbor" guidelines and request for public comment.

SUMMARY: The Federal Trade Commission publishes this notice and request for public comment concerning proposed self-regulatory guidelines submitted by the Children's Advertising Review Unit ("CARU") of the Council of Better Business Bureaus, Inc. under the safe harbor provision of the Children's Online Privacy Protection Rule, 16 CFR § 312.10.

DATES: Written comments must be submitted on or before May 30, 2000. Comments will be posted on the Commission's website: <http://www.ftc.gov>.

ADDRESSES: Written comments should be submitted to: Secretary, Federal Trade Commission, Room H-159, 600 Pennsylvania Avenue, N.W., Washington, DC 20580. The Commission requests that commenters submit the original plus five copies, if feasible. To enable prompt review and public access, comments also should be submitted, if possible, in electronic form, on either a 5¼ or a 3½ inch computer disk, with a disk label stating the name of the commenter and the name and version of the word processing program used to create the document. (Programs based on DOS or Windows are preferred. Files from other operating systems should be submitted in ASCII text format.) Alternatively, the Commission will accept comments submitted to the following e-mail address, safeharbor@ftc.gov. Individual members of the public filing comments need not submit multiple copies or comments in electronic form. All submissions should be captioned: "CARU Safe Harbor Proposal—Comment, P004504."

FOR FURTHER INFORMATION CONTACT: Loren G. Thompson, (202) 326-2049, Abbe Goldstein, (202) 326-3423, or Karen J. Mandel, (202) 326-2491, Division of Advertising Practices, Bureau of Consumer Protection, Federal Trade Commission, 601 Pennsylvania Ave., NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION:**Section A. Background**

On October 20, 1999, the Commission issued its final Rule¹ pursuant to the Children's Online Privacy Protection Act, 15 U.S.C. 6501, *et seq.* The Rule requires certain web site operators to post privacy policies, provide notice, and obtain parental consent prior to collecting, using, or disseminating personal information from children. The Rule contains a "safe harbor" provision enabling industry groups or others to submit self-regulatory guidelines that would implement the protections of the Rule to the Commission for approval.²

Pursuant to Section 312.10 of the Rule, CARU has submitted proposed self-regulatory guidelines to the Commission for approval. The full text of the proposed guidelines is available on the Commission's website, www.ftc.gov.

Section B. Questions on the Proposed Guidelines

The Commission is seeking comment on various aspects of the proposed guidelines, and is particularly interested in receiving comment on the questions that follow. These questions are designed to assist the public and should not be construed as a limitation on the issues on which public comment may be submitted. Responses to these questions should cite the number and subsection of the questions being answered. For all comments submitted, please provide any relevant data, statistics, or any other evidence, upon which those comments are based.

1. Please provide comment on any or all of the provisions in the proposed guidelines. For each provision commented on please describe (a) The impact of the provision(s) (including any benefits and costs), if any, and (b) what alternatives, if any, CARU should consider, as well as the costs and benefits of those alternatives.

2. Do the provisions of the proposed guidelines governing operators' information practices provide "the same or greater protections for children" as those contained in Sections 312.2-312.8 of the Rule?³ Where possible, please cite the relevant sections of both the Rule and the proposed guidelines.

3. Are the mechanisms used to assess operators' compliance with the guidelines effective?⁴ If not, please describe (a) How the proposed guidelines could be modified to satisfy the Rule's requirements, and (b) the

costs and benefits of those modifications.

4. Are the incentives for operators' compliance with the guidelines effective?⁵ If not, please describe (a) How the proposed guidelines could be modified to satisfy the Rule's requirements, and (b) the costs and benefits of those modifications.

5. Do the guidelines provide adequate means for resolving consumer complaints? If not, please describe (a) How the proposed guidelines could be modified to resolve consumer complaints adequately, and (b) the costs and benefits of those modifications.

or
By direction of the Commission.

Donald S. Clark,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Office of the Secretary****Agency Information Collection Activities: Submission for OMB Review; Comment Request**

The Department of Health and Human Services, Office of the Secretary publishes a list of information collections it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) and 5 CFR 1320.5. The following are those information collections recently submitted to OMB.

1. HHS Acquisition Regulations—HHSAR Subpart 315 Solicitation and Receipt of Proposals and Quotations—0990-0139—Extension with no change—Subpart 315.4 is needed to ensure consistency in all Departmental solicitations and to ensure that all solicitations describe all of the information which an offeror would need to submit an acceptable proposal. Respondents: State or local governments, Businesses or other for profit organizations, non-profit institutions, small businesses; Total Number of Respondents: 6,645; Frequency of Response: one time; Average Burden per Response: 2 hours; Estimated Annual Burden: 13,290 hours.

OMB Desk Officer. Allison Eydt.

Copies of the information collection packages listed above can be obtained by calling the OS Reports Clearance Officer on (202) 690-6207. Written

¹ 64 Fed. Reg. 59888 (1999).

² See 16 CFR § 312.10; 64 Fed. Reg. at 59906-59908, 59915.

³ See 16 CFR § 312.10(b)(1); 64 Fed. Reg. at 59915.

⁴ See 16 CFR § 312.10(b)(2); 64 Fed. Reg. at 59915.

⁵ See 16 CFR § 312.10(b)(3); 64 Fed. Reg. at 59915.

comments and recommendations for the proposed information collection should be sent directly to the OMB desk officer designated above at the following address: Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street N.W., Washington, D.C. 20503.

Comments may also be sent to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue S.W., Washington, DC 20201. Written comments should be received within 30 days of this notice.

Dated: April 20, 2000.

Dennis P. Williams,

Deputy Assistant Secretary, Budget.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00048]

Patient Follow-Up Study of Prevention of the Joint Complications of Hemophilia; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2000 funds for a cooperative agreement program for the Mountain State Regional Hemophilia Treatment Center (MSRHTC), University of Colorado Health Sciences Center to conduct a follow-up study of patients enrolled in a trial of primary prophylactic therapy for the prevention of joint disease in children with hemophilia. CDC is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the focus areas of Diabetes. For the conference copy of "Healthy People 2010", visit the internet site <http://www.health.gov/healthypeople>.

The purpose of the program is to provide continued assistance MSRHC in the follow-up of patients enrolled in the current randomized, controlled trial of primary prophylaxis in previously untreated patients with severe hemophilia A and no demonstrable factor VIII inhibitors. Cost and efficacy of early intervention to prevent joint complications should be determined in

the treatment groups and should be compared to similar data from appropriately treated, control subjects. The cumulative risk of factor VIII inhibitor development should be determined for each treatment group and total costs and complication rates ascertained as well. Molecular characterization of factor VIII defects in an effort to predict which subjects will develop inhibitors should be carried out.

Further, follow-up of patients will continue to improve understanding of specific public health issues and enhance preparedness to meet changes.

B. Eligible Applicants

Assistance will be provided only to the MSRHTC. No other applications are solicited. The MSRHTC was the only applicant that applied under the original Program Announcement 95019 and was subsequently awarded. It is the only Hemophilia Treatment Center (HTC) capable of carrying out the follow-up of the hemophilia patients enrolled in this clinical trial because they began and continue the enrollment of patients under the original clinical trial. The enrollment of Hemophilia patients for this program will be completed on September 29, 2000, and it is the intention of CDC to allow for a smooth transition into this follow-up study.

MSRHTC already possesses the necessary data required for the follow-up study for the prevention of the joint complications of hemophilia. MSRHTC's patient data is proprietary, and no other HTC would have ready access.

C. Availability of Funds

Approximately \$250,000 is available in FY 2000 to fund this award. It is expected that the award will begin on or about September 30, 2000 and will be made for a 12-month budget period within a project period of up to 4 years. The funding estimate may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. (Recipient Activities), and CDC will be responsible for the activities listed under 2. (CDC Activities).

1. Recipient Activities

a. Develop standardized study protocols, data collection instruments,

interview questionnaires, progress report forms.

b. Train study coordinators and medical personnel in methods of data collection and patient assessment in the use of standard data abstraction instruments, in techniques of reviewing medical records, in interviewing patients, and in other methods of data collection as appropriate and provided for in the study protocols. It is the responsibility of the recipient to ensure uniform training of study personnel at all data collection sites. The recipient must ensure that the data is collected in a uniform manner at all data collection sites.

c. Develop appropriate management and evaluation systems to ensure that study personnel use data collection and interview instruments according to standard study protocols.

d. Collect and edit all data from all sites, including cost effectiveness data.

e. Obtain sufficient clinical specimens for specialized laboratory analysis and genetic testing, including plasma and cell pellets, to meet the requirements of the study.

f. Develop papers and publish the results.

2. CDC Activities

a. Provide consultation, scientific and technical assistance in planning and implementing the study protocol, as requested. This assistance may include the development of study protocols, data abstraction instruments, interview questionnaires, consent forms, support in statistical and epidemiologic methods to conduct data analysis, and development of the clinical laboratory specimen testing.

b. Assist in the development of a research protocol for Institutional Review Board (IRB) review by all institutions participating in the research project. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

c. Collaborate in the planning, coordination, and facilitation of initial and periodic meetings.

d. Perform sufficient clinical specimens for specialized laboratory analysis and genetic testing, including plasma and cell pellets, as requested.

E. Application Content

Use the information in the Purpose, Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. The application should describe MSRHTC's ability to address the purpose and required activities of this announcement. The application