

appetite, increases fat burning, or slows carbohydrate absorption; causes weight loss in overweight or obese children ages 6 and over; or causes weight loss by suppressing appetite, increasing fat burning, or slowing carbohydrate absorption, when taken by overweight or obese children ages 6 and over. Part IB of the order pertains to Fabulously Feminine. It requires that proposed respondent possess and rely on competent and reliable scientific evidence to support claims that Fabulously Feminine or any other covered product or service will increase a woman's libido, sexual desire, or sexual satisfaction.

Part II of the proposed order requires that proposed respondent possess and rely on competent and reliable scientific evidence to support benefits, performance, or efficacy claims for covered products or services defined as any dietary supplement, food, drug, or device, and any health-related service or program promoting weight loss or sexual enhancement.

Part III of the proposed order prohibits proposed respondent from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test or studies. Part IV of the proposed order permits proposed respondent to make certain claims for drugs or dietary supplements that are permitted in labeling under laws and/or regulations administered by the U.S. Food and Drug Administration.

The remainder of the proposed order contains standard requirements that proposed respondent maintain advertising and any materials relied upon as substantiation for any representation covered by substantiation requirements under the order; distribute copies of the order to certain company officials and employees; and file one or more reports detailing his compliance with the order. Part IX of the proposed order is a provision whereby the order, absent certain circumstances, terminates twenty years from the date of issuance.

The purpose of this analysis is to facilitate public comment on the proposed order, and is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

By direction of the Commission.

**Donald S. Clark,**  
*Secretary.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

#### Meeting of the National Advisory Council for Healthcare Research and Quality

**AGENCY:** Agency for Healthcare Research and Quality (AHRQ).

**ACTION:** Notice of public meeting.

**SUMMARY:** In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the National Advisory Council for Healthcare Research and Quality.

**DATES:** The meeting will be held on Friday, July 30, 2004, from 9 a.m. to 4 p.m. and is open to the public.

**ADDRESSES:** The meeting will be held at The Hubert H. Humphrey Building, Room 800, 200 Independence Avenue, SW., Washington, DC 20201.

**FOR FURTHER INFORMATION CONTACT:** Deborah Queenan, Coordinator of the Advisory Council, at the Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland, 20850, (301) 427-1330. For press-related information, please contact Karen Migdail at (301) 427-1855.

If sign language interpretation or other reasonable accommodation for a disability is needed, please contact Mr. Donald L. Inniss, Director, Office of Equal Employment Opportunity Program, Program Support Center, on (301) 443-1144 no later than April 23, 2004. Agenda, roster, and minutes are available from Ms. Bonnie Campbell, Committee Management Officer, Agency for Healthcare Quality and Research, 540 Gaither Road, Rockville, Maryland 20850. Her phone number is (301) 427-1554. Minutes will be available after August 16, 2004.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Purpose**

Section 921 of the Public Health Service Act (42 U.S.C. 299c) established the National Advisory Council for Healthcare Research and Quality. In accordance with its statutory mandate, the Council is to advise the Secretary of the Department of Health and Human Services and the Director, Agency for Healthcare Research and Quality (AHRQ), on matters related to actions of the Agency to enhance the quality, improve the outcomes, reduce the costs of health care services, improve access to such services through scientific research, and to promote improvements in clinical practice and in the

organization, financing, and delivery of health care services.

The Council is composed of members of the public appointed by the Secretary and Federal ex-officio members.

## **II. Agenda**

On Friday, July 30, 2004, the meeting will begin at 9 a.m., with the call to order by the Council Chair. The Director, AHRQ, will present the status of the Agency's current research, programs, and initiatives. Tentative agenda items include a discussion led by David J. Brailer, M.D., Ph.D., newly appointed National Health Information Technology Coordinator for DHHS, who will discuss the information technology goals for the Department, and a discussion of enhancements to AHRQ's available web-based information tools. The official agenda will be available on AHRQ's Web site at <http://www.ahrq.gov> no later than July 19, 2004. The meeting will adjourn at 4 p.m.

Dated: July 13, 2004.

**Carolyn M. Clancy,**  
*Director.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

#### Contract Review Meeting

In accordance with section 10(a) of the Federal Advisory Committee Act as amended (5 U.S.C., Appendix 2), announcement is made of an Agency for Healthcare Research and Quality (AHRQ) Technical Review Committee (TRC) meeting. This TRC's charge is to review contract proposals and provide recommendations to the Director, AHRQ, with respect to the technical merit of proposals submitted in response to a Request for Proposals (RFP) regarding "Health Information Technology Resource Center (HITRC)". The RFP was published in the Federal Business Opportunities on June 14, 2004.

The upcoming TRC meeting will be closed to the public in accordance with the Federal Advisory Committee Act (FACA), section 10(d) of 5 U.S.C., Appendix 2, FACA regulations, 41 CFR 101-6.1023 and procurement regulations, 48 CFR 315.604(d). The discussions at this meeting of contract proposals submitted in response to the above-referenced RFP are likely to reveal proprietary information and

personal information concerning individuals associated with the proposals. Such information is exempt from disclosure under the above-cited FACA provision and procurement rules that protect the free exchange of candid views and facilitate Department and Committee operations.

*Name of TRC:* The Agency for Healthcare Research and Quality—“Health Information Technology Resource Center (HITRC)”.

*Date:* August 12 and 13, 2004 (Closed to the public).

*Place:* Agency for Healthcare Research and Quality, 540 Gaither Road, Conference Center, Rockville, Maryland 20850.

*Contact Person:* Anyone wishing to obtain information regarding this meeting should contact Steve Bernstein, Center for Primary Care, Prevention, and Clinical Partnerships, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland 20850, 301-427-1581.

Dated: July 1, 2004.

**Carolyn M. Clancy,**

*Director.*

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**BILLING CODE 4160-90-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60Day-04-JP]

**Proposed Data Collections Submitted for Public Comment and Recommendations**

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, or to send comments contact Sandi Gambescia, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-E11, Atlanta, GA 30333 or send an e-mail to [omb@cdc.gov](mailto:omb@cdc.gov).

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information

technology. Written comments should be received within 60 days of this notice.

**Proposed Project**

Risk Factors for Acute Hepatitis B or Acute Hepatitis C in Older Adults—New—National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC).

Questionnaires and data collection forms have been designed to collect information over a 24-month period regarding risk factors for acute hepatitis B or acute hepatitis C in persons age ≥60 years. The purpose of the project is to evaluate the possible associations between healthcare-related exposures and sporadic cases of acute hepatitis B or acute hepatitis C among older adults. The results of the project will assist CDC in accomplishing the part of its mission related to preparing recommendations for the prevention and control of viral hepatitis and its sequelae.

The respondent universe will include residents of a defined geographic area served by the participating public health agency, along with their healthcare providers. Persons identified as meeting the case definition for acute hepatitis B or C age ≥60 years will be asked to participate. Controls will be randomly selected through random digit dialing from among persons age ≥60 years in the general population. For consenting cases and controls, medical record reviews and healthcare provider interviews will be conducted in connection with healthcare-related exposures. There is no cost to respondents.

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)	Total burden hours
Consenting Adults Meeting Case/Control Criteria .....	160	1	30/60	80
Healthcare Providers .....	120	1	20/60	40
<b>Total .....</b>	<b>280</b>	<b>.....</b>	<b>.....</b>	<b>120</b>