

Dated: April 16, 2010.

Judith Sparrow,

Office of Programs and Coordination Office of the National Coordinator for Health Information Technology.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; HIT Policy Committee's Workgroup Meetings; Notice of Meetings

AGENCY: Office of the National Coordinator for Health Information Technology, HHS.

ACTION: Notice of meetings.

This notice announces forthcoming subcommittee meetings of a Federal advisory committee of the Office of the National Coordinator for Health Information Technology (ONC). The meetings will be open to the public via dial-in access only.

Name of Committees: HIT Policy Committee's Workgroups: Meaningful Use, Privacy & Security Policy, Strategic Plan, Adoption/Certification, and Nationwide Health Information Infrastructure (NHIN) workgroups.

General Function of the Committee: To provide recommendations to the National Coordinator on a policy framework for the development and adoption of a nationwide health information technology infrastructure that permits the electronic exchange and use of health information as is consistent with the Federal Health IT Strategic Plan and that includes recommendations on the areas in which standards, implementation specifications, and certification criteria are needed.

Date and Time: The HIT Policy Committee Workgroups will hold the following public meetings during May 2010: May 4th Meaningful Use Workgroup, 10 a.m. to 12 p.m./ET; May 7th Privacy & Security Policy Workgroup, 2 p.m. to 4 p.m./ET; May 10th NHIN Workgroup, 10 a.m. to 1 p.m./ET; and May 11th Strategic Plan Workgroup, 9 a.m. to 11 a.m./ET.

Location: All workgroup meetings will be available via webcast; for instructions on how to listen via telephone or Web visit <http://healthit.hhs.gov>. Please check the ONC Web site for additional information as it becomes available.

Contact Person: Judy Sparrow, Office of the National Coordinator, HHS, 330 C Street, SW., Washington, DC 20201, 202-205-4528, Fax: 202-690-6079, e-mail: judy.sparrow@hhs.gov. Please call the contact person for up-to-date information on these meetings. A notice in the **Federal Register** about last minute modifications that affect a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice.

Agenda: The workgroups will be discussing issues related to their specific subject matter, e.g., meaningful use, the NHIN, privacy and security policy, adoption/certification, or strategic planning. If background materials are associated with the workgroup meetings, they will be posted on ONC's Web site prior to the meeting at <http://healthit.hhs.gov>.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the workgroups. Written submissions may be made to the contact person on or before two days prior to the workgroups' meeting date. Oral comments from the public will be scheduled at the conclusion of each workgroup meeting. Time allotted for each presentation will be limited to three minutes. If the number of speakers requesting to comment is greater than can be reasonably accommodated during the scheduled open public session, ONC will take written comments after the meeting until close of business on that day.

If you require special accommodations due to a disability, please contact Judy Sparrow at least seven (7) days in advance of the meeting.

ONC is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://healthit.hhs.gov> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (Pub. L. 92-463, 5 U.S.C., App. 2).

Dated: April 16, 2010.

Judith Sparrow,

Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-10-09BC]

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, call 404-639-5960 or send comments to Maryam Daneshvar, CDC Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail to 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

Exploring HIV Prevention Communication Among Black Men Who Have Sex with Men In New York City: Project BROTHA—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and Tuberculosis Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is requesting OMB approval to administer a survey, conduct interviews and offer HIV rapid testing in Black Men who have sex with Men (BMSM) and other Men who have Sex with Men (MSM) in New York City. The purpose of the proposed study is to assess how interpersonal communication within BMSM social networks may be related to risk for HIV infection and attitudes towards HIV testing.

Data collection will occur over the course of 2-3 years. After screening for eligibility, a total of 300 BMSM and other MSM in their social networks will be enrolled in 2 phases: (1) 350 BMSM will be recruited and screened to find 100 eligible BMSM participants, and (2) the 100 first phase participants will then recruit 200 other MSM within their social networks to participate in the second phase. Quantitative surveys will be administered by computers and personal interviews will be conducted to collect qualitative data (at baseline and 3-month follow-up). Participants in both phases will be offered rapid HIV testing, and declining an HIV test will not negatively impact their study participation. The research questions being explored are relevant for understanding how interpersonal communication with members of one's social networks are related to risk for contracting HIV infection and attitudes towards HIV testing.

This study will provide important epidemiologic information useful for the development of HIV prevention

interventions for BMSM. Men will complete a 5-minute eligibility screening interview. The baseline computer-based survey will take 45 minutes. The qualitative interview will take approximately 75 minutes. The

number of respondents who will accept HIV testing is estimated to be 200 (accounting for those who did not test at baseline and those who do not consent to test at follow-up). HIV counseling and rapid testing will take

45 minutes. The 3-month follow-up survey will take approximately 30 minutes; the follow-up qualitative interview will take approximately 45 minutes. There is no cost to the respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN TABLE

Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
BMSM respondents only	Screening interview	750	1	5/60	63
	BMSM and other MSM respondents: Baseline.	ACASI survey interview	300	1	45/60
BMSM and other MSM respondents: 3 month follow-up.	Qualitative interview	300	1	1.25	375
	HIV testing & counseling	200	1	45/60	150
	ACASI survey interview	300	1	30/60	150
	Qualitative interview	300	1	45/60	225
	HIV testing & counseling	200	1	45/60	150
	Total Burden Hours

Dated: April 19, 2010.
Maryam I. Daneshvar,
Acting Reports Clearance Officer, Centers for Disease Control and Prevention.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
 [Docket No. FDA-2010-N-0070]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Agreement for Shipment of Devices for Sterilization

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 26, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the

OMB control number 0910-0131. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, *Daniel.Gittleson@fda.hhs.gov*.
SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Agreement for Shipment of Devices for Sterilization—21 CFR 801.150(e) (OMB Control Number 0910-0131)—Extension

Under sections 501(c) and 502(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351(c) and 352(a)), nonsterile devices that are labeled as sterile but are in interstate transit to a facility to be sterilized are adulterated and misbranded. FDA regulations in § 801.150(e) (21 CFR 801.150(e)) establish a control mechanism by which firms may manufacture and label medical devices as sterile at one establishment and ship the devices in interstate commerce for sterilization at another establishment, a practice that facilitates the processing of devices and is economically necessary for some firms. Under § 801.150(e)(1), manufacturers and sterilizers may sign an agreement containing the following: (1) Instructions for maintaining accountability of the number of units in each shipment; (2) acknowledgment that the devices that are nonsterile are being shipped for further processing; and (3)

specifications for sterilization processing. This agreement allows the manufacturer to ship misbranded products to be sterilized without initiating regulatory action and provides FDA with a means to protect consumers from use of nonsterile products. During routine plant inspections, FDA normally reviews agreements that must be kept for 2 years after final shipment or delivery of devices (§ 801.150(a)(2)). The respondents to this collection of information are device manufacturers and contact sterilizers. FDA's estimate of the reporting burden is based on actual data obtained from industry over the past several years where there are approximately 90 firms subject to this requirement. It is estimated that each of these firms on the average prepares 20 written agreements each year. This estimate varies greatly, from 1 to 100, because some firms provide sterilization services on a part time basis for only one customer while others are large facilities with many customers. The average time required to prepare each written agreement is estimated to be 4 hours. This estimate varies depending on whether the agreement is the initial agreement or an annual renewal, on the format each firm elects to use, and on the length of time required to reach agreement. The estimate applies only to those portions of the written agreement that pertain to the requirements imposed by this regulation. The written agreement generally also includes contractual agreements that are a customary and usual business practice. On the average, the total annual recordkeeping burden is 7,200 hours (90 firms x 20 agreements x 4 hours). The