identity proofing and user authentication. For the purposes of the CPS hearing, identify proofing should be understood to mean *the process of providing sufficient information (e.g., identity history, credentials, and documents) to correctly and accurately verify and establish an identity to be used in an electronic environment (e.g., over the Internet).* For many everyday processes such as applying for a passport or driver's license, identity proofing takes place. To be granted the rights associated with a passport or driver's license, one first needs to provide documents to prove one's identity (*e.g.,* birth certificate). This same principal exists to control access to electronic systems, and it is the intent of this hearing to discuss the types of identity proofing used or recommended to gain access to certain health IT products or services.

For the purposes of the CPS hearing, user authentication should be understood to mean *the process of reliably verifying a claimed or presented identity, often used as way to grant authorized access to data, resources, and other network services.* User authentication takes place after an identity has been successfully proofed (verified by the appropriate authority) and a credential representing that proofed identity has been assigned to an individual. This does not mean the assignment of a unique identifier, but rather it refers to the method any system uses (in a unique way) to differentiate its users (*e.g.,* a separate username) and challenge the user's ability to prove that they are who they claim to be (*e.g.,* knowledge of a password associated with the username).

While responding to the questions below, it is recommended that each response identify (1) The risks and benefits associated with a particular identity proofing and/or user authentication method; (2) the potential costs and/or barriers associated with the method's implementation; and (3) if feasible, quantify the risks, benefits, costs, or barriers discussed in parts 1 and 2, with respect to a health care consumer, provider, other entity, or all. *Responses should be particularly focused on the Community's breakthroughs (pre-populated and consumer-directed medication history and registration summary as part of a personal health record (PHR), access to current and historical laboratory results and interpretations in an electronic health record (EHR), and secure messages between patients and their clinicians).* Where possible, please provide references to any peer reviewed literature that has informed your response.

1. Does an in-person identity proofing process provide greater benefit than automated, on-line processes, or vice-versa? Please explain.

2. Identify and particular concerns regarding the type of information collected for identity proofing or the storage of such information.

3. Should there be different identity proofing and user authentication processes for:

a. A patient versus a clinician. If yes, please explain and identify the scenario;

b. The primary user of a PHR versus a proxy for that user?

4. Are there other industry policies and practices related to identity proofing and user authentication and could be used successfully in any of the Community identified breakthroughs (see above)? If so, please described these policies and specify how these could be implemented in a way that would minimize the risks and maximize the benefits as well as how they would compare to alternative methods in terms of risks, benefits and feasibility of implementation.

5. What is the appropriate balance of access to medical information in electronic form (through the use of stronger identity proofing and user authentication) against the privacy concerns of the consumer/patient? If possible, please discuss comparable programs/efforts in the past that have been successful in doing this?

6. What/how do you see the HHS's role, if any, in establishing guidelines for the health care industry with respect to identity proofing and user authentication? Or should the industry self-police in this area?

7. If private industry EHR or PHR services were to import data from Federal agencies (who are required either by statute or policy to protect data in certain ways), would it be reasonable to expect that the EHR or PHR service provided would comply with Federal information security practices?

8. Should the health care industry adopt the concept of multiple assurance levels when performing identity proofing and user authentication functions, similar to what OMB has defined for the Federal Government in OMB Memorandum M–04–04? When responding to this question, please cite, if possible other models that may exist specifically for health care?

9. Based on your experience (personal/organizational) discuss how identity proofing and user authentication are currently addressed in the Personal Health Record (PHR) market from a technical, policy, and implementation perspective. Please ensure that your answers identify:

a. How the type of PHR (i.e., who provides/sponsors the PHR) could impact the identity proofing and user authentication method chosen;

b. Who is capable of providing data to the PHR;

c. The potential impact the type of data (which may vary in levels of perceived sensitivity, e.g., a medication history that lists a drug for an ear infection versus a drug for HIV) could have on the identity proofing and user authentication method chose; and

d. How data is entered into the PHR, for example, by a health care consumer, or from a provider through a ''push model'' where data is automatically sent to the PHR without a request by the consumer.

10. Based on your experience (personal/organizational) with EHR technology, that can at a minimum provide access to current and historical laboratory results and interpretations, should identify proofing and user authentication methodologies (technical, policy, and implementation) differentiate based upon:

a. The reception method of the data

i. For example: Accessing a laboratory's secure Web site for results and typing them into a patient's EHR vs. automatic population from the lab to the EHR; and

b. The interconnectivity of the EHR

i. For example: A doctor in a large health care system may be able to query another provider's EHR for data as opposed to querying the lab directly.

Written testimony submitted by the public is not required to address all of the questions listed above, and answers to any or all of the questions will be accepted so long as they comply with the following testimony guidelines. Persons wishing to submit written testimony (*which should not exceed eight double-spaced typewritten pages*) should endeavor to submit it by September 29, 2006.

If you have special needs for the meeting or require further assistance, please contact (202) 690–7151 and reference the CPS meeting.

The meeting will be available via Web cast at *www.eventcenterlive.com/cfmx/ec/login/login1.cfm?BID=67* [Room Number: 8285166].

Judith Sparrow,

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

[FR Doc. 06–7657 Filed 9–13–06; 8:45 am]

BILLING CODE 4150–24–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-06–06BO]

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 and send comments to Seleda Perryman, CDC Assistant 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

Survey of Surgeons on Occupational Exposure to Blood and Body Fluids—New—National Center for Infectious Diseases (NCID), Division of Healthcare Quality Promotion (DHQP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Division of Healthcare Quality Promotion (DHQP), CDC, defines as its primary mission the protection of patients and healthcare personnel through the promotion of safety, quality, and value in the healthcare delivery system. One priority is preventing transmission of blood borne pathogens to healthcare personnel during delivery of medical care. The purpose of this project is to conduct a survey of surgeons regarding the occurrence, reporting, and management of occupational exposures to blood and body fluid in the operating room (OR) setting. Respondents will also be asked about safety perceptions and practices during surgery.

The survey is intended to assess the knowledge, attitudes, and behaviors of surgeons regarding sharps injuries and blood exposures in the operating room setting, post exposure management and treatment of blood and body fluid exposures, and safety culture and practices. Data from the National Surveillance System for Health Care Workers (NaSH) indicate that surgeons are at high risk for sharps injuries and/or blood and body fluid exposures. However, they have the lowest rates of exposure reporting. The results of the proposed survey will be used to determine the nature and frequency of blood exposures in the operating room setting and to make recommendations about mechanisms for improving safety culture and practices in this setting.

The questionnaire will be sent to a 5% sample of the 99,042 U.S. surgeons in the American Medical Association's physician masterfile. The survey sample will be stratified by sub-specialty and geographic region. Assuming a 20% response rate, the total number of respondents would be 990. The survey will take a maximum of 10 minutes to complete. Therefore, the maximum total burden hours may reach 165. There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (hours)
Surgeons	990	1	10/60	165

Dated: September 7, 2006.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E6–15235 Filed 9–13–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

FDA 225–06–8402

Memorandum of Understanding Between the United States Food and Drug Administration and the National Cancer Institute

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The purpose of this Memorandum of Understanding (MOU) is to set forth an agreement between the National Cancer Institute (NCI) and the Food and Drug Administration (FDA) (collectively ''the Parties'', or individually as a ''Party'') to develop and implement the Federal Investigator Registry of Biomedical Information Research Data (FIREBIRD), which will enable clinical investigators, NCI, FDA, and industry entities sponsoring clinical trials of investigational drugs (''Sponsors of Drugs and Biologics'' or ''Sponsors'') to manage clinical investigator information electronically in a fully secure manner.

DATES: The agreement became effective August 10, 2006.

FOR FURTHER INFORMATION CONTACT:

For FDA: Randy Levin, Center for Drug Evaluation and Research (HF–18), Food and Drug Administration, 5600 Fishers Lane, rm. 14B–45, Rockville, MD 20857, 301–827–7784, FAX: 301–827–1540.

For NCI: Peter Covitz, National Cancer Institute, 6116 Executive Blvd., rm. 705, Rockville, MD 20892, 301–402–0326.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: September 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S