

on HIV/AIDS (PACHA) will hold a meeting. The meeting will be open to the public.

DATES: The meeting will be held July 25, 2012 from 3:00 p.m. to approximately 5:00 p.m. (EDT).

ADDRESSES: 801 K Street NW., Washington, DC, 20001.

FOR FURTHER INFORMATION CONTACT: Mr. Melvin Joppy, Committee Manager, Presidential Advisory Council on HIV/AIDS, Department of Health and Human Services, 200 Independence Avenue SW., Room 443H, Hubert H. Humphrey Building, Washington, DC 20201; (202) 690-5560. More detailed information about PACHA can be obtained by accessing the Council's Web site www.aids.gov/pacha.

SUPPLEMENTARY INFORMATION: PACHA was established by Executive Order 12963, dated June 14, 1995 as amended by Executive Order 13009, dated June 14, 1996. The Council was established to provide advice, information, and recommendations to the Secretary regarding programs and policies intended to promote effective prevention of HIV disease and AIDS. The functions of the Council are solely advisory in nature.

The Council consists of not more than 25 members. Council members are selected from prominent community leaders with particular expertise in, or knowledge of, matters concerning HIV and AIDS, public health, global health, philanthropy, marketing or business, as well as other national leaders held in high esteem from other sectors of society. Council members are appointed by the Secretary or designee, in consultation with the White House Office on National AIDS Policy. The agenda for the upcoming meeting will be posted on the Council's Web site at www.aids.gov/pacha.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact person. Pre-registration for public attendance is advisable and can be accomplished by contacting the PACHA Committee Manager at melvin.joppy@hhs.gov. Members of the public will have the opportunity to provide comments at the meeting. Any individual who wishes to participate in the public comment session must register with Melvin Joppy at melvin.joppy@hhs.gov; registration for public comment will not be accepted by telephone. Public comment will be limited to two minutes per speaker. Any members of the public who wish to have

printed material distributed to PACHA members at the meeting should submit, at a minimum, 1 copy of the materials to the Committee Manager, PACHA, no later than close of business Wednesday, July 18, 2012. Contact information for the PACHA Committee Manager is listed above.

Dated: July 5, 2012.

B. Kaye Hayes,

Executive Director, Presidential Advisory Council on HIV/AIDS.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "American Recovery and Reinvestment Act "Developing a Registry of Registries"." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3521, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on February 23rd, 2012 and allowed 60 days for public comment. Several comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by August 10, 2012.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395-6974 (attention: AHRQ's desk officer) or by email at OIRA_submission@omb.eop.gov (attention: AHRQ's desk officer).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

American Recovery and Reinvestment Act "Developing a Registry of Registries"

The Food and Drug Administration Modernization Act of 1997, Public Law 105-115, provided for the creation of a Clinical Trials Data Bank, known as *ClinicalTrials.gov*. Since its launch in 2000, the *ClinicalTrials.gov* system has registered over 90,500 trials. The large volume of studies currently listed in *ClinicalTrials.gov* and the high usage numbers suggest that the system has been successful at improving access to information about clinical studies. However, while *ClinicalTrials.gov* supports the listing of observational studies, such listing is not required.

Patient registries are a distinct type of observational study. Patient registries may be designed for many purposes, such as to observe the natural history of disease, examine comparative effectiveness, or fulfill post-approval commitments. Patient registries have specific characteristics that are not currently captured on *ClinicalTrials.gov*. To date, some registry sponsors have attempted to leverage the observational study model to post patient registry-type records on *ClinicalTrials.gov*. However, stakeholders have noted that the system does not fully meet their needs.

Patient registries have received significant attention and funding in recent years. Similar to controlled interventional studies, patient registries represent some burden to patients (e.g., time to complete patient reported outcome measures, risk of loss of privacy), who often participate voluntarily in hopes of improving knowledge about a disease or condition. Patient registries also represent a substantial investment of health research resources. Despite these factors, registration of patient registries in *ClinicalTrials.gov* is not currently required, presenting the potential for duplication of efforts and insufficient dissemination of findings that are not published in the peer-reviewed literature. To ensure that resources are used in the most efficient manner, registries need to be listed in a manner similar to that of trials in *ClinicalTrials.gov*.

By creating a central point of collection for information about all patient registries in the United States, the Registry of Patient Registries (RoPR) helps to further AHRQ's goals by making information regarding quality, appropriateness, and effectiveness of health services (and patient registries in

particular) more readily available and centralized.

The primary goal of this project is to engage stakeholders in the design and development of a RoPR database system that is compatible with ClinicalTrials.gov and meets the following objectives:

(1) Provides a searchable database of patient registries in the United States (to promote collaboration, reduce redundancy, and improve transparency);

(2) facilitates the use of common data fields and definitions in similar health conditions (to improve opportunities for sharing, comparing, and linkage);

(3) provides a public repository of searchable summary results (including results from registries that have not yet been published in the peer-reviewed literature);

(4) offers a search tool to locate existing data that researchers can request for use in new studies; and serves as a recruitment tool for researchers and patients interested in participating in patient registries.

This study is being conducted by AHRQ through its contractor, the Outcome DEcIDE Center, pursuant to the American Recovery and Reinvestment Act, Pub. L. 111–5, and pursuant to AHRQ’s statutory authority to conduct and support research and disseminate information on health care and on systems for the delivery of such care, including activities with respect to

the quality, effectiveness, efficiency, appropriateness and value of health care services and with respect to database development. 42 U.S.C. 299a(a)(1) and (8).

Method of Collection

To achieve the goals of this project the following data collections will be implemented:

(1) Collect information from registry holders, defining a patient registry profile via a Web-based interface, to populate the RoPR database system.

The purpose of the RoPR is to create a readily available public resource in the model of ClinicalTrials.gov to share information on existing patient registries to promote collaboration, reduce redundancy, and improve transparency in registry research. Patient registry research has become more prevalent and, based on stakeholder feedback, is not adequately served by ClinicalTrials.gov at present. The information being collected in the RoPR record will be visible to the public visiting the RoPR Web site and will be available for public use in this capacity.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden for the respondents’ time to participate in the RoPR. Because the RoPR is a voluntary system available to any entity conducting a patient registry, it is not possible to determine the number of potential respondents.

We do know that over 3,800 newly registered records designated as “observational studies” were entered into ClinicalTrials.gov in 2010. Only a subset of this number (which we will estimate at a maximum of 40%) would qualify as patient registries and would likely be registered in the RoPR. Therefore, we use 1,520 (3,800* 0.40) in Exhibits 1 and 2 below as a very rough, but high, estimation of the potential number of respondents who will enter registries into the RoPR annually. The actual number of respondents will depend on a variety of factors and could vary widely. It should be remembered that mandates could evolve making registration in the RoPR mandatory. Our estimates therefore attempt to factor an upper threshold for volume.

Each respondent will enter a new RoPR record only once and is estimated to take 45 minutes. An estimated 50% (760 records) of RoPR records will be updated once a year and will take about 15 minutes. This estimate is based on a query of ClinicalTrials.gov which showed that about 50% of observational studies registered in ClinicalTrials.gov had been updated in the past year. The total respondent burden is estimated to be 1,330 hours annually.

Exhibit 2 shows the estimated cost burden associated with the respondent’s time to participate in the RoPR. The total cost burden is estimated to be \$45,579 annually.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
New RoPR Record	1,520	1	45/60	1,140
Review/update RoPR Record	760	1	15/60	190
Total	2,280	na	na	1,330

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
New RoPR Record	1,520	1,140	\$34.27	\$39,068
Review/update RoPR Record	760	190	34.27	6,511
Total	2,280	1,330	na	45,579

* Based upon the mean average wage for Healthcare Practitioners and Technical Occupations, May 2010 National Occupational Employment and Wage Estimates, U.S. Department of Labor, Bureau of Labor Statistics. Available at: http://www.bls.gov/oes/current/oes_nat.htm#29-0000.

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the estimated total and annualized cost to the government to create and maintain the RoPR for 3 years. The total cost is estimated to be \$3,184,333.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

Cost component	Total cost	Annualized cost
Project Development	\$2,318,509	\$772,836
Project Management	409,149	136,383
Overhead	456,675	152,225
Total	3,184,333	1,061,444

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: July 5, 2012.

Carolyn M. Clancy,

Director.

[FR Doc. 2012-16849 Filed 7-10-12; 8:45 am]

BILLING CODE 4160-90-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-12-0842]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy, call the CDC Reports Clearance Officer at (404) 639-7570 or send an email to *omb@cdc.gov*. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-6974. Written comments should be received within 30 days of this notice.

Proposed Project

STD Surveillance Network (SSuN)- (OMB 0920-0842 Exp: 1/31/2013)— Revision—National Center for HIV/ AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The purpose of the STD Surveillance Network (SSuN) project is to improve the capacity of national, state, and local STD programs to detect, monitor, and respond rapidly to trends in STDs through enhanced collection, reporting, analysis, visualization and interpretation of disease information. The objectives of the SSuN Project are (1) To establish an integrated network of sentinel STD clinics and health departments to inform and guide national programs and policies for STD control in the U.S.; (2) to improve the capacity of national, state and local STD programs to detect, monitor and respond to established and emerging trends in STDs, HIV, and viral hepatitis; and (3) to identify and evaluate the effectiveness of public health interventions to reduce STD morbidity.

The SSuN Project is an active STD sentinel surveillance network comprised of 12 surveillance sites around the United States. SSuN uses two surveillance strategies to collect

information. The first is a STD clinic-based surveillance which extracts data from existing electronic medical records for all patient visits at participating STD clinics. The second is a population-based surveillance in which a sample of individuals reported with gonorrhea to the 12 SSuN state or city health departments are interviewed using locally-designed interview templates.

For the clinic-based surveillance, the specified data elements are abstracted on a quarterly basis from existing electronic medical records for all patient visits to participating clinics. Data in the electronic medical record may be collected at time of registration, during the clinic encounter, or through laboratory testing. For the population-based STD surveillance, the results of interviews will be entered into a developed Microsoft Access database that will be adapted locally for each clinic. High quality, informative, and timely surveillance data are necessary to guide STD programs so interventions are designed and implemented appropriately. Furthermore, surveillance data are necessary for understanding the impact of STD interventions based on the epidemiology of each STD.

This information is collected to establish an integrated network of sentinel STD clinics and health departments to inform and guide national programs and policies for STD control in the U.S. It will improve the capacity of national, state, and local STD programs to detect, monitor, and respond to established and emerging trends in STDs, HIV, and viral hepatitis. SSuN will help identify and evaluate the effectiveness of public health interventions to reduce STD morbidity.

The SSuN surveillance platform allows CDC to establish and maintain common standards for data collection, transmission, and analysis, and to build and maintain STD surveillance expertise in 12 surveillance areas. Such common systems, established mechanisms of communication, and in-place expertise are all critical components for timely, flexible, and high quality surveillance.

There is no cost to respondents other than their time. The total estimated annual burden hours are 480.

ESTIMATED ANNUALIZED BURDEN HOURS

Types of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
SSuN site	12	4	2