

discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment doesn't include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment doesn't include any sensitive health information, like medical records or other individually identifiable health information. In addition, don't include any "[t]rade secret or any commercial or financial information which is obtained from any person and which is privileged or confidential * * *," as provided in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, don't include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c). Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online, or to send them to the Commission by courier or overnight service. To make sure that the Commission considers your online comment, you must file it at <https://ftcpublic.commentworks.com/ftc/apparelrulespra2>, by following the instructions on the web based form. If this Notice appears at <http://www.regulations.gov>, you also may file a comment through that Web site.

If you file your comment on paper, write "Apparel Rules: FTC File No. P074201" on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade Commission, Office of the Secretary, Room H-113 (Annex J), 600 Pennsylvania Avenue NW., Washington, DC 20580. If possible, submit your

paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at <http://www.ftc.gov> to read this Notice. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before March 26, 2012. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at <http://www.ftc.gov/ftc/privacy.shtm>.

Comments on the information collection requirements subject to review under the PRA should also be submitted to OMB. If sent by U.S. mail, address comments to: Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for the Federal Trade Commission, New Executive Office Building, Docket Library, Room 10102, 725 17th Street, NW., Washington, DC 20503. Comments sent to OMB by U.S. postal mail, however, are subject to delays due to heightened security precautions. Thus, comments instead should be sent by facsimile to (202) 395-5167.

Willard K. Tom,
General Counsel.

[FR Doc. 2012-4141 Filed 2-22-12; 8:45 am]

BILLING CODE 6750-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Subcommittee on Population Health Meeting.

Time and Date:

March 8, 2012: 9 a.m.–5:30 p.m. EST;

March 9, 2012: 9 a.m.–3 p.m. EST.

Place: National Center for Health Statistics, 3311 Toledo Road, Auditorium, Hyattsville, MD 20782, Tel: 301-458-4200.

Status: Open.

Purpose: The purpose of this meeting is to gain input about the collection of socioeconomic (SES) data in federal surveys, including innovative uses of information. The intention is to describe SES measures, review SES data collection in federal surveys and provide recommendations for SES data collection within HHS.

Contact Person for More Information: Substantive program information as well as

summaries of meetings and a roster of committee members may be obtained from Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 2402, Hyattsville, Maryland 20782, telephone (301) 458-4245. Information also is available on the NCVHS home page of the HHS Web site: <http://www.ncvhs.hhs.gov/>, where further information including an agenda will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458-4EEO (4336) as soon as possible.

Dated: February 14, 2012.

James Scanlon,

Deputy Assistant Secretary for Planning and Evaluation, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2012-4118 Filed 2-22-12; 8:45 am]

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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.

DATES: Comments on this notice must be received by April 23, 2012.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at doris.lefkowitz@AHRQ.hhs.gov.

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, Public Law 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

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
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 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: February 6, 2012.

Carolyn M. Clancy,

Director.

[FR Doc. 2012-3911 Filed 2-22-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Mechanical Prophylaxis of Venous Thromboembolism (VTE)

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

ACTION: Request for Scientific Information Submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from manufacturers of antithrombotic medical devices. Scientific information is being solicited to inform our Comparative Effectiveness of Pharmacologic and Mechanical

Prophylaxis of Venous Thromboembolism Among Special Populations Review, which is currently being conducted by the Evidence-based Practice Centers for the AHRQ Effective Health Care Program. Access to published and unpublished pertinent scientific information on this device will improve the quality of this comparative effectiveness review. AHRQ is requesting this scientific information and conducting this comparative effectiveness review pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173.

DATES: Submission Deadline on or before March 26, 2012.

ADDRESSES: Online submissions: <http://effectivehealthcare.AHRQ.gov/index.cfm/submitscientific-information-packets/>. Please select the study for which you are submitting information from the list of current studies and complete the form to upload your documents.

Email submissions: ehcsrc@ohsu.edu (please do not send zipped files—they