

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](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]

**BILLING CODE 4160-90-M**

**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](mailto:ehcsrc@ohsu.edu) (please do not send zipped files—they

are automatically deleted for security reasons).

*Print submissions:* Robin Paynter, Oregon Health and Science University, Oregon Evidence-based Practice Center, 3181 SW Sam Jackson Park Road, Mail Code: BICC, Portland, OR 97239-3098.

**FOR FURTHER INFORMATION CONTACT:**

Robin Paynter, Research Librarian, Telephone: 503-494-0147 or Email: [ehcsrc@oahsu.edu](mailto:ehcsrc@oahsu.edu).

**SUPPLEMENTARY INFORMATION:** In accordance with Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, the Agency for Healthcare Research and Quality has commissioned the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a comparative effectiveness review of the evidence for pharmacologic and mechanical prophylaxis of venous thromboembolism (VTE) among special populations.

The EHC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by systematically requesting information (e.g., details of studies conducted) from medical device industry stakeholders through public information requests, including via the **Federal Register** and direct postal and/or online solicitations. We are looking for studies that report on mechanical prophylaxis of venous thromboembolism among special populations, including those that describe adverse events, as specified in the key questions detailed below. The entire research protocol, including the key questions, is also available online at: <http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=928#4370>.

This notice is a request for industry stakeholders to submit the following:

- A current product label, if applicable (preferably an electronic PDF file).
- Information identifying published randomized controlled trials and observational studies relevant to the clinical outcomes. Please provide both a list of citations and reprints if possible.
- Information identifying unpublished randomized controlled trials and observational studies relevant to the clinical outcomes. If possible, please provide a summary that includes the following elements: study number, study period, design, methodology, indication and diagnosis, proper use

instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to withdrawn/follow-up/analyzed, and effectiveness/efficacy and safety results.

- Registered ClinicalTrials.gov studies. Please provide a list including the ClinicalTrials.gov identifier, condition, and intervention.

Your contribution is very beneficial to this program. AHRQ is not requesting and will not consider marketing material, health economics information, or information on other indications.

This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

In addition to your scientific information please submit an index document outlining the relevant information in each file along with a statement regarding whether or not the submission comprises all of the complete information available.

**Please Note:** The contents of all submissions, regardless of format, will be available to the public upon request unless prohibited by law.

The draft of this review will be posted on AHRQ's EHC program Web site and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: <http://effectivehealthcare.AHRQ.gov/index.cfm/join-the-email-list1/>.

### The Key Questions

#### Question 1

What is the comparative effectiveness and safety of Inferior Vena Cava filters to prevent Pulmonary Emboli in hospitalized patients with trauma?

#### Question 2

1. What is the comparative effectiveness and safety of pharmacologic and mechanical strategies to prevent VTE in hospitalized patients with traumatic brain injury?

2. What is the optimal timing of initiation and duration of pharmacologic prophylaxis to prevent VTE in hospitalized patients with traumatic brain injury?

#### Question 3

What is the comparative effectiveness and safety of pharmacologic and mechanical strategies to prevent VTE in hospitalized patients with burns?

#### Question 4

What is the comparative effectiveness and safety of pharmacologic and mechanical strategies to prevent VTE in hospitalized patients with liver disease?

#### Question 5

What is the comparative effectiveness and safety of pharmacologic and mechanical strategies to prevent VIE in hospitalized patients receiving antiplatelet therapy?

#### Question 6

What is the comparative effectiveness and safety of pharmacologic and mechanical strategies to prevent VTE in patients having bariatric surgery?

#### Question 7

What is the comparative effectiveness and safety of pharmacologic prophylaxis for prevention of VTE during hospitalization of obese and underweight patients?

#### Question 8

What is the comparative effectiveness and safety of pharmacologic prophylaxis for prevention of VTE during hospitalization of patients with acute kidney injury, moderate renal impairment, or severe renal impairment not undergoing dialysis and patients receiving dialysis?

Dated: February 7, 2012.

**Carolyn M. Clancy,**

*Director, AHRQ.*

[FR Doc. 2012-3937 Filed 2-21-12; 8:45 am]

**BILLING CODE 4160-90-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[30-Day—12-0213]

### 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 requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995. To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-7570 or send an email to [omb@cdc.gov](mailto: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

National Vital Statistics Report Forms (0920-0213, Expiration 04/30/2012)—Extension—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).