

are automatically deleted for security reasons).

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**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- Information identifying unpublished randomized controlled trials and observational studies relevant to the clinical outcomes.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primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to withdrawn/follow-up/analyzed, and effectiveness/efficacy and safety results.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.

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## 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).

**Background and Brief Description**

The compilation of national vital statistics dates back to the beginning of the 20th century and has been conducted since 1960 by the Division of Vital Statistics of the National Center for Health Statistics, CDC. The collection of the data is authorized by 42 U.S.C. 242k. This submission requests approval to collect the monthly and annually summary statistics for three years.

The Monthly Vital Statistics Report forms provide counts of monthly occurrences of births, deaths, infant deaths, marriages, and divorces. Similar data have been published since 1937 and are the sole source of these data at the National level. The data are used by the Department of Health and Human Services and by other government, academic, and private research and commercial organizations in tracking changes in trends of vital events. The

respondents are the registration officials in the 50 States, the District of Columbia, New York City, Puerto Rico, Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. In addition, 33 local (county) officials in New Mexico who record marriages occurring and divorces and annulments granted in each county of New Mexico will use this form. This form, which takes about 10 minutes to complete, is designed to collect counts of monthly occurrences of births, deaths, infant deaths, marriages, and divorces immediately following the month of occurrence.

The Annual Vital Statistics Occurrence Report Form collects final annual counts of marriages and divorces by month for the United States and for each State. The statistical counts requested on this form differ from provisional estimates obtained on the Monthly Vital Statistics Report Form in

that they represent complete counts of marriages, divorces, and annulments occurring during the months of the prior year. These final counts are usually available from State or county officials about eight months after the end of the data year. The data are widely used by government, academic, private research, and commercial organizations in tracking changes in trends of family formation and dissolution. The 58 Respondents for the Annual Vital Statistics Occurrence Report Form, which takes about 30 minutes to complete, are registration officials in each State and Territory, the District of Columbia, and New York City.

There are no costs to respondents other than their time to participate; the data are routinely available in each reporting office as a by-product of ongoing activities. The total estimated annualized burden hours are 211.

TABLE 1—ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents                               | Form name                                       | Number of respondent | Number of responses per respondents | Average burden per response (in hours) |
|---|---|----------------------|-------------------------------------|--|
| State, Territory and New Mexico County officials. | Monthly Vital Statistics Report .....           | 91                   | 12                                  | 10/60                                  |
| State, Territory and Other officials .....        | Annual Vital Statistics Occurrence Report ..... | 58                   | 1                                   | 30/60                                  |

**Kimberly S. Lane,**

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

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60 Day-12-0010]

**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 404-639-7570 and send comments to Kimberly Lane, CDC Reports Clearance Officer, 1600 Clifton

Road, MS-D74, Atlanta, GA 30333 or send an email 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**

The National Birth Defects Prevention Study (NBDPS), (OMB 0920-0010)—Reinstatement Without Change—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

CDC has been monitoring the occurrence of serious birth defects and

genetic diseases in Atlanta since 1967 through the Metropolitan Atlanta Congenital Defects Program (MACDP). The MACDP is a population-based surveillance system for birth defects in the 5 counties of Metropolitan Atlanta. Its primary purpose is to describe the spatial and temporal patterns of birth defects occurrence and serves as an early warning system for new Teratogens.

The National Birth Defects Prevention Study (NBDPS) formerly the Birth Defects Risk Factor Surveillance Study (BDRFS) began in 1997. The NBDPS is a case-control study of major birth defects that includes cases identified from existing birth defect surveillance registries in nine states, including metropolitan Atlanta. NBDPS control infants are randomly selected from birth certificates or birth hospital records. Mothers of case and control infants are interviewed using a computer-assisted telephone interview. The interview takes approximately one hour to complete. A maximum of four hundred interviews are planned per year per center, 300 cases and 100 controls resulting in a maximum interview burden of 400 hours for each of the centers each year.