

Proposed Merger is consummated. If the Commission determines that Integra is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires the parties to unwind the sale of rights to Integra and then divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products as required.

The Order also requires the parties to appoint Quantic Regulatory Services, LLC as interim monitor to ensure the parties comply with the obligations pursuant to the Consent Agreement and to keep the Commission informed about the status of the transfer of the assets and rights to Integra.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2015-25604 Filed 10-7-15; 8:45 am]

BILLING CODE 6750-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[60Day-16-15BHD; Docket No. CDC-2016-0088]

#### Proposed Data Collection Submitted for Public Comment and Recommendations

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on Congenital Heart Surveillance to Recognize Outcomes, Needs and well-being (CHSTRONG). CDC seeks to collect data for the purpose of providing insight into the public health questions that remain for

the population and to develop services and allocate resources to improve long-term health and wellbeing.

**DATES:** Written comments must be received on or before December 7, 2015.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2016-0088 by any of the following methods:

- *Federal eRulemaking Portal:*

*Regulation.gov.* Follow the instructions for submitting comments.

- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., MS-D74, Atlanta, Georgia 30329.

*Instructions:* All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: *omb@cdc.gov*.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

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; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

#### Proposed Project

Congenital Heart Surveillance To Recognize Outcomes, Needs, and Well-being (CHSTRONG)—New—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

Congenital heart defects (CHDs) are the most common type of structural birth defects, affecting approximately 1 in 110 live-born children. In prior decades, many CHDs were considered fatal during infancy or childhood, but with tremendous advances in pediatric cardiology and cardiac surgery, at least 85% of patients now survive to adulthood and there are approximately 1.5 million adults with CHD living in the United States. With vast declines in mortality from pediatric heart disease over the past 30 years, it is vital to evaluate long term outcomes and quality of life issues for adults with CHD. However, U.S. data on long term outcomes, quality of life issues, and comorbidities of adults born with CHD are lacking. U.S. data is needed to provide insight into the public health questions that remain for this population and to develop services and allocate resources to improve long-term health and wellbeing.

For this one-year project, we will use data from U.S. state birth defect surveillance systems to identify a population-based sample of individuals 18 to 45 years of age born with CHD. We will then use state databases and online search engines to find current addresses for those individuals and mail surveys to them inquiring about their barriers to

health care, quality of life, social and educational outcomes, and transition of care from childhood to adulthood. The information collected from this population-based survey will be used to inform current knowledge, allocate resources, develop services, and,

ultimately, improve long-term health of adults born with CHD.

We estimate identifying 7,500 individuals with CHD in the birth defects surveillance systems, obtaining current addresses and sending surveys to 5,625 individuals with CHD (75%), and receiving completed surveys from 4,500 individuals (80%). The survey

takes approximately 25 minutes to complete, which includes 5 minutes to read the informed consent and 20 minutes to answer survey questions. Therefore, we estimate the total burden hours are 1,875.

There are no costs to participants other than their time.

#### ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondent         | Form name              | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden hours |
|----------------------------|------------------------|-----------------------|------------------------------------|----------------------------------------|--------------------|
| Individuals with CHD ..... | Informed consent ..... | 4,500                 | 1                                  | 5/60                                   | 375                |
| Individuals with CHD ..... | Survey .....           | 4,500                 | 1                                  | 20/60                                  | 1,500              |
| Total .....                | .....                  | .....                 | .....                              | .....                                  | 1,875              |

#### Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Centers for Disease Control and Prevention

[60 Day-16-15BHH; Docket No. CDC-2016-0087]

#### Proposed Data Collection Submitted for Public Comment and Recommendations

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the Personal Protective Equipment Information (PPE-Info) Database which is a compendium of personal protective equipment (PPE) Federal regulations and consensus standards.

**DATES:** Written comments must be received on December 7, 2015.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2016-0087 by any of the following methods:

**Federal eRulemaking Portal:** *Regulation.gov*. Follow the instructions for submitting comments.

**Mail:** Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329.

**Instructions:** All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

**Please note:** All public comment should be submitted through the Federal eRulemaking portal (*Regulations.gov*) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: [omb@cdc.gov](mailto:omb@cdc.gov).

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed

extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

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; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.