DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–16–16UW; Docket No. CDC–16–0031]

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 effort 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 proposed information collection request entitled ''Case Investigation of Cervical Cancer (CICC) Study,'' which is designed to identify self-reported barriers and facilitators to cervical cancer screening and follow-up among women diagnosed with invasive cervical cancer. Medical charts will also be reviewed to further evaluate verify screening and follow-up of abnormal tests results prior to diagnosis.

DATES: Written comments must be received on or before May 23, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2016–0031 by any of the following methods:

- *Federal eRulemaking Portal:* Regulations.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.*

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

Case Investigation of Cervical Cancer (CICC) Study—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Invasive cervical cancer occurs when cervical cancer spreads from the surface of the cervix to deeper cervical tissue or to other parts of the body. In the United States, invasive cervical cancer is largely preventable due to the availability of (1) screening tests, which allow for early detection and treatment of cervical precancers, and (2) a vaccine that prevents infection with types of human papillomavirus (HPV) which are associated with over 80% of cervical cancers. However, one previous study showed that half of the women who developed cervical cancer had not been adequately screened, and a more recent study showed that there were still approximately 8 million women in the U.S. who had not been screened for cervical cancer in the previous five years.

CDC plans to conduct the Case Investigation of Cervical Cancer (CICC) study to improve understanding of the facilitators and barriers to cervical cancer screening and timely follow-up to abnormal test results. The study is designed to address the following research questions: (1) Did women get a cervical cancer screening test during the five years prior to cervical cancer diagnosis? (2) What were facilitators or barriers to getting a screening test? (3) Did women get recommended follow-up of an abnormal test in a timely manner? (4) What were the facilitators or barriers to getting follow-up for an abnormal test? (5) What were the women's patterns when seeking medical care (*i.e.,* routine medical care or symptoms)?

To answer these questions, CDC will collect and analyze information from three sources, in collaboration with central cancer registries (CCR) in three states and a contract research organization.

First, CCR will use existing information to recruit participants who are eligible for the study, *i.e.,* women who were diagnosed with invasive cervical cancer between January 1, 2014 and December 31, 2016. Information about tumor characteristics, date of diagnosis, and cancer stage is already maintained by CCR and reported to CDC (National Program of Cancer Registries: Cancer Surveillance System, OMB Control No. 0920–0469).

Second, women who agree to participate in the CICC study will be asked to complete a survey assessing facilitators and barriers to screening and follow-up health care. The estimated

burden per response for completing the mail-in questionnaire is 15 minutes. In addition, respondents will be asked to provide contact information for all health care providers they have seen in the five years prior to their diagnosis with cervical cancer, and to complete a Health Insurance Portability and Accountability Act (HIPAA) Release form that allows study staff to access the medical records maintained by these providers. For each CICC participant, the estimated burden per response for the health care provider list and HIPAA Release form is five minutes.

Third, medical chart abstractors will collect information from the health care providers who provided relevant services to study participants in the five years prior to their diagnosis with invasive cervical cancer. The medical record abstraction process does not entail burden to study participants, or to the medical chart abstractors who will review the medical charts on a fee-for-service basis. The medical record abstraction process does entail additional recordkeeping burden to office assistants for health care providers, who are required to maintain records of disclosures of medical information, *e.g.,* the HIPAA Release Form for the CICC study. The estimated burden for support activities associated with each medical record abstraction is five minutes.

CDC has identified three states as potential study sites. Based on preliminary data from their state cancer registries, a total of approximately 1,670 eligible cervical cancer survivors are eligible for participation. CDC estimates a survey response rate of 50% of across the entire sample (N = 835) followed by an 80% acceptance of medical chart verification (N = 668). These estimates yield approximately 668 women with complete data for both surveys and chart verification. For each CICC participant, the medical chart abstraction process is expected to require follow-up with 1–5 (average of 3) health care providers (N = 2004).

Findings from this study will be used to inform interventions targeted to reach women who are never or rarely screened for cervical cancer. Study findings will be disseminated through reports, presentations, and publications. Results will also be used by participating sites, CDC, and other federal agencies to improve services provided to women at risk of invasive cervical cancer.

OMB approval is requested for two years. All personal identifier information will be maintained by the cancer registries where it is stored as part of the standard registry data repository. No identifiable information will be collected by CDC or CDC's main contractor. Participation is voluntary and there are no costs to respondents 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 (in hours)
Invasive cervical cancer survivors	Case Investigation of Cervical Cancer Study Survey.	418	1	15/60	105
	HIPAA Release and Listing of medical providers in last 5 years.	314	1	5/60	28
Health care office assistant	Support for medical record abstraction.	1,002	1	5/60	84
Total	.....	.....	.....	.....	217

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

[60Day–16–16VB; Docket No. CDC–2016–0032]

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 a proposed information collection request entitled ''HIV Knowledge, Beliefs, Attitudes, and Practices of Providers in the Southeast (K–BAP Study)''. CDC is requesting a three-year approval for new data collection to identify areas of HIV prevention knowledge and practice strengths and deficits among primary care providers, in order to target limited HIV prevention resources to achieve the greatest reduction in new HIV infections and optimize HIV clinical care in clinical settings. The target population will be primary care providers practicing in high-prevalence metropolitan statistical geographic areas with large at-risk African American populations.

DATES: Written comments must be received on or before May 23, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2016–0032 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.