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.

[FR Doc. 2016–06706 Filed 3–23–16; 8:45 am]

BILLING CODE 4163–18–P

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.

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

HIV Knowledge, Beliefs, Attitudes, and Practices of Providers in the Southeast (K–BAP Study)—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Persons at high risk of HIV infection have often had one or more contacts with a health care provider within a year of their diagnoses. These health care encounters represent missed opportunities to: (1) Review and discuss sexual health and risk reduction, (2) screen for HIV infection and other STDs, (3) recognize and diagnose acute HIV infection and offer immediate antiretroviral therapy (ART) if indicated, (4) discuss the prevention benefit of treatment (with subsequent referral or prescription) and re-engagement in care, as appropriate, and (5) provide PrEP and nPEP if not infected and at high risk, consistent with current HIV prevention guidelines and recommendations.

Health care providers in high-prevalence geographic areas could substantially reduce new HIV infections among the patient populations they serve, as well as their communities. Health care providers are a trusted source of reliable information. They also have the capacity to perform STD/HIV testing and to prescribe medication with appropriate clinical follow-up.

Review of the literature published between January 2000 and June 2014 indicates we know little about providers' knowledge, beliefs, attitudes, and practices (K–BAP) in at-risk jurisdictions about HIV risk, HIV diagnosis and antiretroviral drug interventions in these domains, especially primary care providers serving high-risk patients in high-prevalence communities. K–BAP Study is an effort to assess providers' K–BAP using a cross sectional survey in the five priority HIV prevention domains noted above.

This K–BAP Study aligns with multiple goals and objectives of the National HIV/AIDS Strategy (NHAS) and CDC's ''winnable battles.''

The project's specific objectives are to (1) Characterize knowledge, beliefs, attitudes, and practices of providers in five key HIV prevention domains in high-HIV prevalence communities with disproportionate numbers of blacks/African Americans, and (2) Educate providers about prevention interventions related to these domains based on survey-identified knowledge, beliefs, attitudes, and practices of providers' deficits.

The respondent population of medical providers will be pulled from the Healthcare Data Solutions (HDS) ProviderPRO and MidLevelPRO databases. Respondents will be recruited to participate in the survey through a combination of emails and phone calls. This strategy will consist of four emails spaced one week apart followed by phone calls to non-responders. The emails will explain the purpose of the survey, the availability of continuing education (CE) credits, and the $20 cash token of appreciation.

A large two-part internet-based survey will be conducted among a representative random sample of providers in the selected six (6) metropolitan statistical areas (MSAs) with the highest HIV burden among the African American population. Part one of survey will be administered to participants at the beginning of project. The part-one survey findings will used to identify providers' knowledge, beliefs, attitudes, and practices of providers that might require additional educational reinforcement. Based on survey responses, providers will be linked to continuing education (CE) credit-eligible educational modules to improve their educational deficits. The educational modules are all web-based using either video or case-based methods of learning. The length of the course range from 1–3 hours accounting for 0.25—1.0 credit hours. Part two of survey will be administered six months later comprising of only the core questions in part one of survey to assess impact of CE modules on providers' practices regarding HIV prevention and treatment.

There are no costs to respondents other than their time. The total annual burden hours are 1,172.

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)
Providers	K–BAP Provider Baseline Screener and Survey.	1,827	1	29/60	883
Providers	K–BAP Provider Follow-Up Screener and Survey.	914	1	19/60	289
Total					1,172

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.

[FR Doc. 2016–06707 Filed 3–23–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3662]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Reagents for Detection of Specific Novel Influenza A Viruses

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by April 25, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0584. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance on Reagents for Detection of Specific Novel Influenza A Viruses—21 CFR Part 866 OMB Control Number 0910–0584—Extension

In accordance with section 513 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c), FDA evaluated an application for an in vitro diagnostic device for detection of influenza subtype H5 (Asian lineage), commonly known as avian flu. FDA concluded that this device is properly classified into class II in accordance with section 513(a)(1)(B) of the FD&C Act, because it is a device for which the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, but there is sufficient information to establish special controls to provide such assurance. The statute permits FDA to establish as special controls many different things, including postmarket surveillance, development and dissemination of guidance recommendations, and ''other appropriate actions as the Secretary deems necessary'' (section 513(a)(1)(B) of the FD&C Act). This information collection is a measure that FDA determined to be necessary to provide reasonable assurance of safety and effectiveness of reagents for detection of specific novel influenza A viruses.

FDA issued an order classifying the H5 (Asian lineage) diagnostic device into class II on March 22, 2006 (71 FR 14377), establishing the special controls necessary to provide reasonable assurance of the safety and effectiveness of that device and similar future devices. The new classification was codified in 21 CFR 866.3332, a regulation that describes the new classification for reagents for detection of specific novel influenza A viruses and sets forth the special controls that help to provide a reasonable assurance of the safety and effectiveness of devices classified under that regulation. The regulation refers to the special controls guidance document entitled ''Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses,'' which provides recommendations for measures to help provide a reasonable assurance of safety and effectiveness for these reagents. The guidance document recommends that sponsors obtain and analyze postmarket data to ensure the continued reliability of their device in detecting the specific novel influenza A virus that it is intended to detect, particularly given the propensity for influenza viruses to mutate and the potential for changes in disease prevalence over time. As updated sequences for novel influenza A viruses become available from the World Health Organization, National Institutes of Health, and other public health entities, sponsors of reagents for detection of specific novel influenza A viruses will collect this information, compare them with the primer/probe sequences in their devices, and incorporate the result of these analyses into their quality management system, as required by 21 CFR 820.100(a)(1). These analyses will be evaluated against the device design validation and risk analysis required by 21 CFR 820.30(g) to determine if any design changes may be necessary.

FDA estimates that 10 respondents will be affected annually. Each respondent will collect this information twice per year; each response is estimated to take 15 hours. This results in a total data collection burden of 300 hours.

The guidance also refers to previously approved information collections found in FDA regulations. The collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 807 subpart E have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR