Dated: March 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–15–15UX: Docket No. CDC–2015–0011]

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 ''Continuing and New International and U.S. Data Collections from the 2014 CDC Ebola Virus Disease Emergency Response''. Under the current 60-day **Federal Register** Notice, the CDC is announcing its intention to seek three-year OMB approval to continue several Ebola-related information collections beyond their current emergency expiration dates and to conduct newly proposed information collections within international borders of Ebola-affected West African countries and within the domestic borders of State, Territorial and Local (STL) public health authorities in the U.S. These existing ''source'' information collections and new information collection requests (ICRs) will be submitted under four ''destination'' ICRs for Office of Management and Budget (OMB) approval.

DATES: Written comments must be received on or before May 26, 2015.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2015–0011, 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

Continuing and New International and U.S. Data Collections from the 2014 CDC Ebola Virus Disease Emergency Response—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The international outbreak of Ebola virus disease (EVD) in West Africa began March 10, 2014. The initial cases were from southern Guinea, near its rural border with Liberia and Sierra Leone. Highly mobile populations contributed to increasing waves of person-to-person transmission of EVD that occurred in multiple countries in West Africa. The Centers for Disease Control and Prevention (CDC) Emergency Operations Center (EOC) was activated on July 9, 2014, to help coordinate technical assistance and control activities with international partners and to deploy teams of public health experts to the affected countries.

The operations turned to the United States (U.S.) when the first imported case of EVD was diagnosed in Texas on September 30, 2014. In response, on October 11, 2014, the CDC Quarantine Stations and the Department of Homeland Security (DHS) Customs and Border Patrol (CBP) mobilized to screen, detect, and refer arriving travelers who were potential persons at risk for EVD to appropriate state, territorial, and local (STL) authorities. The CDC also increased its commitment to support STL public health authorities to combat and control the spread of EVD within their jurisdictions.

Thus in 2014, the CDC used OMB emergency clearance procedures to initiate and expedite multiple urgently needed information collections in West Africa, at U.S. ports of entry, and within STL jurisdictions. These procedures allowed the agency to accomplish its primary mission on many fronts to quickly prevent public harm, illness,

and death from the uncontrolled spread of EVD.

With this notice, the CDC is announcing its intention to seek three-year OMB clearances to continue several Ebola-related information collections beyond their current emergency expiration dates and to conduct newly proposed information collections within international borders of Ebola-affected West African countries and within the domestic borders of STL public health authorities in the U.S. These existing ''source'' information collections and new ICRs will be submitted under four ''destination'' ICRs for OMB approval.

On the international front, CDC seeks to continue to address key public health surveillance and medical treatment objectives in collaboration with West African ministries of health (MoHs), the World Health Organization (WHO), and other key partners. Examples of ''source'' information collections include: (1) ''2014 Emergency Response to Ebola in West Africa'' (OMB Control No. 0920–1033, expiration date 4/30/2015) which helped to establish country EVD surveillance systems for case investigations and contact tracing; and (2) the emergency clearance for ''Household Transmission Survey—a Public Health Response Evaluation in Western Area, Sierra Leone'' (OMB Control No. 0920–1043, expiration date 07/31/2015). This was a one-time investigation that will be the first of a new ''destination'' generic clearance ICR that will identify ways to improve established surveillance systems in other West African countries and settings.

On the domestic front, CDC's information collections will focus on continued support of STL public health authorities and healthcare providers in EVD infection control and notifiable disease reporting to the CDC. CDC wishes to extend OMB clearance for the ''source'' emergency information collection, ''Ebola Virus Disease in the United States: CDC Support for Case and Contact Investigation'' (OMB Control Number 0920–1045, expiration date: 07/31/2015). For this, the CDC proposes a new ''destination'' ICR titled ''National Disease Surveillance Program III—CDC Support for Case Investigations, Contact Tracing, and Case Reports.'' This new mechanism will be designed to allow CDC to conduct active disease surveillance in support of and at the request of STL authorities among respondents that may include the general public, workers, and STL authorities.

The CDC will seek OMB approval for another new domestic ICR titled ''CDC Emergency Operations Center Clinical Inquiries'' an Ebola-related information collection currently in use without an OMB control number. Early in the response, a call center was quickly set up to support urgent inquiries about active monitoring, diagnosis, and clinical treatment of EVD. The clinical inquirers were STL authorities and health facilities that were notified by U.S. Quarantine Stations that persons requiring investigation and possible treatment for EVD were arriving in their respective jurisdictions and facilities.

Although initiated by EOC Task Forces, the lead CDC center for the emergency response (based on subject matter, mission, and program areas) will sponsor these information collections. These information collections will align with their legislative authority, which is Section 301 of the Public Health Service Act (42 U.S.C. 241).

There are no costs to the respondents other than their time. The total annualized burden requested is 378,695 hours.

Estimated Annualized Burden Hours

A—CDC International Emergency Response Case and Contact Surveillance Systems

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
General Public	A1—Viral Hemorrhagic Fever Case Investigation Form (English).	13,650	1	20/60	4,550
General Public	A2—Viral Hemorrhagic Fever Case Investigation Form (French).	7,350	1	20/60	2,450
General Public	A3—Viral Hemorrhagic Fever Case Investigation Short Form (English).	5,850	1	10/60	975
General Public	A4—Viral Hemorrhagic Fever Case Investigation Short Form (French).	3,150	1	10/60	525
General Public	A5—Viral Hemorrhagic Fever Contact Listing Form (English).	19,500	1	15/60	4,875
General Public	A6—Viral Hemorrhagic Fever Contact Listing Form (French).	10,500	1	15/60	2,625
General Public	A7—Viral Hemorrhagic Fever Contact Tracing Follow-Up Form (English).	195,000	1	63/60	204,750
General Public	A8—Viral Hemorrhagic Fever Contact Tracing Follow-Up Form (French).	105,000	1	63/60	110,250
General Public	A9—Ebola Virus Disease Case Contact Questionnaire (English).	195,000	1	5/60	16,250
General Public	A10—Ebola Virus Disease Case Contact Questionnaire (French).	105,000	1	5/60	8,750
General Public	A11—Ebola Outbreak Response Sexual Transmission Adult Case Investigation Form (English).	500	1	30/60	250
General Public	A12—Ebola Outbreak Response Sexual Transmission Adult Case Investigation Form (French).	300	1	30/60	150
Healthcare Workers or Proxy.	A13—Healthcare Worker Ebola Virus Disease Exposure Report—West Africa (CDC–WHO) (English).	1,950	1	30/60	975
Healthcare Workers or Proxy.	A14—Healthcare Worker Ebola Virus Disease Exposure Report—West Africa (CDC–WHO) (French).	1,050	1	30/60	525

A—CDC International Emergency Response Case and Contact Surveillance Systems—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Healthcare Workers or Proxy.	A15—Healthcare Worker Ebola Virus Investigation Questionnaire (Liberia).	400	1	30/60	200
Healthcare Workers or Proxy.	A16—Healthcare Worker Ebola Virus Disease Exposure Report (Sierra Leone).	400	1	30/60	200
Healthcare Workers or Proxy.	A17—Health Facility Assessment and Case Finding Survey (English).	3,900	1	30/60	1,950
Healthcare Workers or Proxy.	A18—Health Facility Assessment and Case Finding Survey (French).	2,100	1	30/60	1,050
Total					361,300

B—Generic Clearance for "Household Transmission Surveys in West Africa: Public Health Response Evaluations"

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Case-patients or caregiver (as proxy).	B1—Initial Questionnaire for Case-Patients—SAMPLE FORM.	357	1	20/60	119
Heads of household	B2—Questionnaire for Ebola-affected Households—SAMPLE FORM.	357	1	20/60	119
Household contacts of case-patient.	B3—Questionnaire for Investigation of Household Contacts of Ebola-infected Case-patients—SAMPLE FORM.	3,570	1	30/60	1,785
Household contacts of case-patient.	B4—Contact Exit Questionnaire—SAMPLE FORM.	3,570	1	5/60	298
Laboratory analyst and project staff.	B5—Patient Laboratory Record—SAMPLE FORM.	573	1	5/60	48
Total					2,369

C—"National Disease Surveillance Program III—CDC Support for Case Investigation, Contact Tracing, and Case Reports"

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
General Public—Case	C1—Ebola Virus Disease Case Investigation Form—United States.	15	1	30/60	8
General Public—Case	C2—Symptom Monitoring Form	15	57	5/60	72
General Public—Person Under Investigation (PUI).	C3—Ebola Virus Disease Person Under Investigation (PUI) Form.	300	1	10/60	50
General Public—Person Under Investigation (PUI).	C2—Symptom Monitoring Form	300	42	5/60	1,050
General Public—Contact	C4—Ebola Virus Disease Contact Tracing Form—United States.	105	1	10/60	18
General Public—Contact	C2—Symptom Monitoring Form	105	42	5/60	368
Healthcare Workers	C5—Ebola Virus Disease Tracking Form for Healthcare Workers with Direct Patient Contact.	600	15	10/60	1,500
Healthcare Workers	C2—Symptom Monitoring Form	600	57	5/60	2,850
Laboratory Personnel	C6—Ebola Tracking Form for Laboratory Personnel.	600	15	10/60	1,500
Laboratory Personnel	C2—Symptom Monitoring Form	600	57	5/60	2,850
Environmental Services Personnel.	C7—Ebola Tracking Form for Environmental Services Personnel.	600	15	10/60	1,500
Environmental Services Personnel.	C2—Symptom Monitoring Form	600	57	5/60	2,850

C—"NATIONAL DISEASE SURVEILLANCE PROGRAM III—CDC SUPPORT FOR CASE INVESTIGATION, CONTACT TRACING, AND CASE REPORTS"—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
State, Territorial, and Local Public Health Authorities and Their Delegates.	C8—Daily and Weekly Report	15	42	10/60	105
Total					14,721

D—"CDC EMERGENCY OPERATIONS CENTER CLINICAL INQUIRIES"

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
State and Local Health Departments.	D1—Clinical Inquiries Database	420	1	15/60	105
Clinicians and Other Providers.	D1—Clinical Inquiries Database	800	1	15/60	200
Total					305

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 Medicare & Medicaid Services

[CMS–3314–N]

Medicare, Medicaid, and CLIA Programs; Announcement of the Re-Approval of the American Osteopathic Association/Healthcare Facilities Accreditation Program (Formerly Known as the American Osteopathic Association) as an Accreditation Organization Under the Clinical Laboratory Improvement Amendments of 1988

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the application of the American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP) for approval as an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program. We have determined that AOA/HFAP meets or exceeds the applicable CLIA requirements. In this notice, we announce the approval and grant AOA/HFAP deeming authority for a period of 6 years.

DATES: *Effective Date:* This notice is effective from March 27, 2015 to March 29, 2021.

FOR FURTHER INFORMATION CONTACT: Kathleen Todd, 410–786–3385.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100–578). CLIA amended section 353 of the Public Health Service Act. We issued a final rule implementing the accreditation provisions of CLIA on July 31, 1992 (57 FR 33992). Under those provisions, we may grant deeming authority to an accreditation organization if its requirements for laboratories accredited under its program are equal to or more stringent than the applicable CLIA program requirements in 42 CFR part 493 (Laboratory Requirements), subpart E of part 493 (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption under an Approved State Laboratory Program), which specifies the requirements an accreditation organization must meet to be approved by CMS as an accreditation organization under CLIA.

II. Notice of Approval of the American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP) as an Accreditation Organization

In this notice, we approve the American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP) as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements for all specialty and subspecialty areas under CLIA. We have examined the initial AOA/HFAP application and all subsequent submissions to determine its accreditation program's equivalency with the requirements for approval of an accreditation organization under subpart E of part 493. We have determined that AOA/HFAP meets or exceeds the applicable CLIA requirements. We have also determined that AOA/HFAP will ensure that its accredited laboratories will meet or exceed the applicable requirements in subparts H, I, J, K, M, Q, and the applicable sections of subpart R. Therefore, we grant AOA/HFAP approval as an accreditation organization under subpart E of part 493, for the period stated in the **DATES** section of this notice for all specialty and subspecialty areas under CLIA. As a result of this determination, any laboratory that is accredited by AOA/HFAP during the time period stated in the **DATES** section of this notice will be deemed to meet the CLIA requirements