Attention: Document Identifier/OMB Control Number, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: November 5, 2009.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–09CD]

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 Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov*. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Laboratory Medicine Best Practices Project (LMBP)—New—National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is seeking approval from the Office of Management and Budget (OMB) to collect information from healthcare organizations in order to conduct a systemic review of laboratory practice effectiveness. The purpose of information collection is to include completed unpublished quality improvement studies/assessments carried out by healthcare organizations (laboratories, hospitals, clinics) in systematic reviews of practice effectiveness. CDC has been sponsoring the Laboratory Medicine Best Practices (LMBP) initiative to develop new systematic evidence review methods for making evidence-based recommendations in laboratory medicine. This initiative supports the CDC's mission of improving laboratory practices.

The focus of the initiative is on pre- and post-analytic laboratory medicine practices that are effective at improving healthcare quality. While evidence-based approaches for decision-making have become standard in healthcare, this has been limited in laboratory medicine. No single evidence-based model for recommending practices in laboratory medicine exists, although the number of laboratories operating in the United States and the volume of laboratory tests available certainly warrant such a model.

The Laboratory Medicine Best Practices Initiative began in October 2006, when DLS convened the Laboratory Medicine Best Practices Workgroup (Workgroup), a multidisciplinary panel of experts in several fields including laboratory medicine, clinical medicine, health services research, and health care performance measurement. The Workgroup has been supported by staff at CDC and the Battelle Memorial Institute under contract to CDC.

To date, the Laboratory Medicine Best Practices (LMBP) project work has been completed over three phases. During Phase 1 (October 2006–September 2007) of the project, CDC staff developed systematic review methods for conducting evidence reviews using published literature, and completed a proof-of-concept test. Results of an extensive search and review of published literature using the methods for the topic of patient specimen identification indicated that an insufficient quality and number of studies were available for completing systematic evidence reviews of laboratory medicine practice effectiveness for multiple practices, and hence for making evidence-based recommendations. These results were considered likely to be generalizable to most potential topic areas of interest.

A finding from Phase 1 work was that laboratories would be unlikely to publish quality improvement projects or studies demonstrating practice effectiveness in the peer reviewed literature, but that they routinely conducted quality improvement projects and had relevant data for completion of evidence reviews. Phase 2 (September 2007–November 2008) and Phase 3 (December 2008–September 2009), involved further methods development and pilot tests to obtain, review, and evaluate published and unpublished evidence for practices associated with the topics of patient specimen identification, communicating critical value test results, and blood culture contamination. Exploratory work by CDC supports the existence of relevant unpublished studies or completed quality improvement projects related to laboratory medicine practices from healthcare organizations. The objective for successive LMBP evidence reviews of practice effectiveness is to supplement the published evidence with unpublished evidence to fill in gaps in the literature.

Healthcare organizations and facilities (laboratory, hospital, clinic) will have the opportunity to voluntarily enroll in an LMBP network and submit readily available unpublished studies, quality improvement projects, evaluations, assessments, and other analyses relying on unlinked, anonymous data using the LMBP Submission Form. LMBP Network participants will also be able to submit unpublished studies/data for evidence reviews on an annual basis using this form. There will be no charge to respondents for their participation, other than their time. The total estimated annualized burden hours for this information collection request are 100 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Healthcare Organizations	150	1	40/60

Dated: November 6, 2009.

Maryam I. Daneshvar,

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

[FR Doc. E9–27335 Filed 11–12–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Criteria for Vaccination Requirements for U.S. Immigration Purposes

AGENCY: Centers for Disease Control and Prevention (CDC).

ACTION: Final notice of agency action.

DATES: This agency action is effective December 14, 2009.

FOR FURTHER INFORMATION CONTACT: Ashley A. Marrone, J.D., U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Division of Global Migration and Quarantine, 1600 Clifton Road, NE. (E03), Atlanta, GA 30333; Telephone, 404–498–1600.

SUMMARY: On April 8, 2009, the Centers for Disease Control and Prevention (CDC) published a notice in the **Federal Register** (74 FR 15986) seeking public comment on proposed criteria that CDC intends to use to determine which vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) for the general U.S. population should be required for immigrants seeking admission into the United States or seeking adjustment of status to that of an alien lawfully admitted for permanent residence. This final notice describes the criteria that CDC has adopted.

At present, CDC requires all vaccinations against vaccine-preventable diseases explicitly listed in section 212(a)(1)(A)(ii) of the Immigration and Nationality Act, as well as all vaccinations recommended by the ACIP for the general U.S. population. After the effective date of this notice, CDC will continue to require the vaccinations explicitly listed in section 212(a)(1)(A)(ii)—mumps, measles, rubella, polio, tetanus and diphtheria toxoids, pertussis, *Haemophilus influenzae* type B, and hepatitis B—and, for all other vaccinations recommended by ACIP for the general U.S. public, CDC will begin requiring only those for which there is a public health need at the time of immigration/change of status based on the following criteria:

1. The vaccine must be an age-appropriate vaccine as recommended by the ACIP for the general U.S. population, and

2. At least one of the following:

a. The vaccine must protect against a disease that has the potential to cause an outbreak.[1]

b. The vaccine must protect against a disease that has been eliminated in the United States or is in the process for elimination in the United States.[2]

SUPPLEMENTARY INFORMATION:

Background

Under section 212(a)(1)(A)(ii) of the Immigration and Nationality Act (INA) (8 U.S.C. 1182(a)(1)(A)(ii)), any alien who seeks admission into the United States as an immigrant, or who seeks adjustment of status to the status of an alien lawfully admitted for permanent residence, is inadmissible into the United States if the alien is unable to present documentation of having received vaccination against ''vaccine-preventable diseases, which shall include at least the following diseases: Mumps, measles, rubella, polio, tetanus and diphtheria toxoids, pertussis, *Haemophilus influenzae* type B, and hepatitis B, and any other vaccinations against vaccine-preventable diseases recommended by the Advisory Committee on Immunization Practices.'' Aliens subject to this provision may apply for a waiver in certain circumstances, e.g., if the vaccination is not medically appropriate or contrary to the alien's religious beliefs or moral convictions.

Medical examinations, including an evaluation to determine whether an alien has received these vaccinations, are authorized under section 232 of the INA (8 U.S.C. 1222). Under sections 212(a)(1) and 232 of the INA (8 U.S.C. 1182(a)(1), 1222), and section 325 of the Public Health Service Act (42 U.S.C. 252), the Department of Health and Human Services (HHS) publishes regulations establishing requirements for the medical examination. The Secretary of HHS has delegated the authority for administering these regulations to the Centers for Disease Control and Prevention (CDC). The regulations are codified in 42 CFR part 34. Panel physicians and civil surgeons, through contractual agreements and by designations with the Department of State (DOS) and the Department of Homeland Security (DHS), respectively, conduct the medical examinations in accordance with these regulations. CDC also publishes Technical Instructions (TIs) for the medical examinations, which must be followed by panel physicians and civil surgeons. The vaccinations required by the INA are listed in the Technical Instructions (*see http://www.cdc.gov/ncidod/dq/technica.htm*).

Since 1996, when the vaccination requirement was added to the INA, CDC has required immigrants subject to the INA vaccination requirement to receive all vaccinations routinely recommended by the Advisory Committee on Immunization Practices (ACIP) for the general U.S. population. Vaccine development has evolved since 1996 and, in addition, a greater number of vaccines are recommended by ACIP than were recommended when the legislation was enacted. As a result, CDC is reassessing which of these vaccinations are appropriate for immigration purposes, taking into consideration both the context in which they are given as well as the interests of public health.

To meet the threshold for consideration, a vaccine must first be an age-appropriate vaccine as recommended by the ACIP for the general U.S. population. After this determination is satisfied, the vaccine must protect against (1) a disease that has the potential to cause an outbreak, and/or (2) a disease that has been eliminated in the United States or is in the process for elimination in the United States. Outbreak is defined as the occurrence of more cases of disease than could be anticipated in a given area or among a specific group of people over a particular period of time. The determination of an outbreak may be made in a variety of scenarios. For example, an outbreak may be determined by comparing the current number of cases of disease with the background rate of the disease. The ''background rate'' of disease is the rate at which the disease usually occurs, at a particular time, in a particular population, or in a particular place. Therefore, the occurrence of a disease above the background rate, so that more people than usual or an unexpected group of people have become ill with the same disease in a given geographic area, or over a given period of time, could be viewed as an outbreak.

In general, and as observed through previous experience, an outbreak is associated with a public health response (e.g., initiation of an investigation,

[1] For purposes of this Notice, ''outbreak'' means the occurrence of more cases of disease than could be anticipated in a given area or among a specific group of people over a particular period of time.

[2] ''Elimination'' is the reduction to zero of the incidence of infection caused by a specific agent in a defined geographic area as a result of deliberate efforts; continued measures to prevent re-establishment of transmission are required.