Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-12-11GU]

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 email to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Survey of Rapid Influenza Diagnostic Test (RIDT) Practices in Laboratories-NEW-the Office of Surveillance, Epidemiology, and Laboratory Services (OSELS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Survey of Rapid Influenza Diagnostic Testing Practices in Laboratories is a national systematic study investigating rapid influenza diagnostic testing practices in clinical laboratories. The survey will be funded in full by the Office of Surveillance, Epidemiology, and Laboratory Services (OSELS) of the Centers for Disease Control and Prevention (CDC).

Influenza epidemics usually cause an average more than 200,000 hospitalizations and 36,000 deaths per year in the U.S. Respiratory illnesses caused by influenza viruses are not easily differentiated from other respiratory infections based solely on symptoms. Also influenza viruses may adversely affect different subpopulations. The effective use of rapid influenza diagnostic testing practices is an important component of the differential diagnosis of influenza-like-illness in both inpatient and outpatient treatment facilities. Test results are used for making decisions about antiviral vs. antibiotic use, and in making admission or discharge decisions. In many cases, rapid influenza tests are the only tests that can provide results while the patient is still present in the facility. Thus, the appropriate use of the tests, and interpretation of test results is critical to the treatment and control of influenza. More than a dozen rapid tests have been approved by the U.S. Food and Drug Administration and are in widespread use. The reliability of rapid influenza tests is influenced by the individual test

product used and the setting. Reported sensitivities range from 10-75%; while the median specificities reported are 90-95%. Other factors influencing accuracy are the stage (or duration) of illness when the diagnostic specimen is collected, type and adequacy of the specimen collected, variability in user technique for specimen collection or assay performance, and disease activity in the community. Given these and other collective findings, it is imperative for public health and for response planning that CDC develops sector-specific guidance and effective outreach to the clinicians on appropriate use of RIDT in their practices.

Previous studies by CDC of outpatient facilities showed that clinical laboratories usually perform the rapid tests for emergency departments, and provide results for both inpatient and outpatient treatment. Thus, understanding the use of rapid influenza testing in clinical laboratories, how the laboratories report results to emergency departments and treatment facilities and health departments, and what quality assurance practices are used will guide future efforts of the CDC to develop appropriate influenza testing guidelines and sector-specific training materials for clinicians and improve health outcomes of the American public.

The survey covers basic laboratory demographic characteristics, specimen collection and processing, testing practices, reporting

of results to emergency departments and other treatment facilities, reporting results to health departments, quality assurance practices, and methods of receiving updated influenza-related information. The majority of the questions request information about laboratory influenza testing practices.

To date, no systematic study has been conducted to investigate how laboratories use these tests, how they report results, or how they interact with outpatient treatment facilities. The survey will be conducted on a national sample of clinical laboratories. There are no costs to respondents except their time. The total estimated annual burden hours are 1020.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs)
Clinical Laboratory Supervisors	Survey of Rapid Influenza Diagnostic Test Practices in Laboratories	2040	1	30/60

DATE: December 1, 2011

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[FR Doc. 2011-31561 Filed 12/07/2011 at 8:45 am; Publication Date: 12/08/2011]