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. 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 of 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

<table>
<thead>
<tr>
<th>Type of respondents</th>
<th>Form name</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Avg. burden per response (in hrs)</th>
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<td>Clinical Laboratory Supervisors</td>
<td>Survey of Rapid Influenza Diagnostic Test Practices in Laboratories.</td>
<td>2040</td>
<td>1</td>
<td>30/60</td>
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We cannot reasonably comply with the requirement of section 1862(a)(1)(A) of the Social Security Act.

We are, however, requesting an emergency review to ensure compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review to ensure compliance with section 1862(a)(1)(A) of the Social Security Act. We cannot reasonably comply with the normal clearance procedures in that public harm is reasonably likely to result if normal clearance procedures are followed as stated in 5 CFR 1320.13(a)(2)(i).

1. Type of Information Collection Request: New collection; Title of Information Collection: Medicare Fee-For-Service Prepayment Medical Review; Use: The information required under this collection is requested by Medicare contractors to determine proper payment or if there is a suspicion of fraud. Medicare contractors request the information from providers or suppliers submitting claims for payment from the Medicare program when data analysis indicates aberrant billing patterns or other information which may present a vulnerability to the Medicare program; Form Number: CMS–10417 (OMB 0938–New); Frequency: Occasionally; Affected Public: Private Sector (Business or other for-profit and Not-for-profit institutions); Number of Respondents: 2,700,000; Total Annual Responses: 2,700,000; Total Annual Hours: 1,360,000. (For policy questions regarding this collection contact Debbie Skinner at (410) 786–7480. For all other issues call (410) 786–1326.)

CMS is requesting OMB review and approval of this collection by December 19, 2011, with a 180-day approval period. Written comments and recommendations will be considered from the public if received by December 15, 2011.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS’ Web Site address at http://www.cms.gov/PaperworkReductionActof1995/PRAL/list.asp or Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be received via one of the following methods by December 15, 2011.

1. Electronically. You may submit your comments electronically to http://www.regulations.gov. Follow the instructions for “Comment or Submission” or “More Search Options” to find the information collection document(s) accepting comments.

2. By regular mail. You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier CMS–10417, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

3. By Email to OMB. OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Email: OIRA_submission@omb.eop.gov.

Dated: December 2, 2011.

Martique Jones,
Director, Regulations Development Group,
Division B, Office of Strategic Operations and Regulatory Affairs.

BILLING CODE 4120–01–P