DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-21-200S]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled “COVID-19 Pandemic Response, Laboratory Data Reporting” to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on June 5th, 2020 to obtain comments from the public and affected agencies. CDC received two comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
(c) Enhance the quality, utility, and clarity of the information to be collected;
(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.
Proposed Project
COVID-19 Pandemic Response, Laboratory Data Reporting – New – National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Efforts are underway to ensure that laboratory data—including diagnostic viral testing data and serologic testing data—are comprehensive and readily available from laboratories and other facilities providing testing, including point-of-care (POC) testing sites for the public health response to SARS-CoV-2 and COVID-19.

Ensuring a rapid and thorough public health response to the COVID-19 pandemic necessitates comprehensive laboratory testing data. These data contribute to understanding disease incidence and trends: initiating epidemiologic case investigations, assisting with contact tracing, assessing availability and use of testing resources, and identifying supply chain issues for reagents and other material. Laboratory testing data, in conjunction with case reports and other data, also provide vital guidance for mitigation and control activities. The total estimated annualized burden is 65,936 hours. There are no costs to respondents other than their time.

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>Average Burden per Response (in hours)</th>
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</thead>
<tbody>
<tr>
<td>State epidemiologist or informatics staff</td>
<td>CDC-provided CSV file or HL7 messages</td>
<td>54</td>
<td>180</td>
<td>1</td>
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<tr>
<td></td>
<td>CDC-provided CSV file or HL7 messages (retrospective data entry)</td>
<td>54</td>
<td>1</td>
<td>4</td>
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<tr>
<td>IT professional</td>
<td>LIMS interface configuration</td>
<td>7,000</td>
<td>1</td>
<td>8</td>
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</tbody>
</table>

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