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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-20-200S; Docket No. CDC-2020-0062]

**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 effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled COVID-19 Pandemic Response, Laboratory Data Reporting. The collection will be used to gather comprehensive laboratory testing data to ensure a rapid and thorough federal response to the COVID-19 pandemic.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2020-0062 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74,

Atlanta, Georgia 30329; phone: 404-639-7570; E-mail:
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 the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. 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 submissions of responses.
5. Assess information collection costs.

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

The Centers for Disease Control and Prevention (CDC) requests an emergency six-month approval for a New Information Collection titled COVID-19 Pandemic Response, Laboratory Data Reporting. 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 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 of 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.

Public Law 116-136 § 18115(a), the Coronavirus Aid, Relief, and Economic Security (CARES) Act, requires “every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19” to report the results from each such test to the Secretary of the Department of Health and Human Services (HHS).

Through the CARES Act, and other coronavirus supplemental funding packages including the Paycheck Protection Program and Health Care Enhancement Act, jurisdictions have received funding to accelerate and improve data collection and reporting of SARS-CoV-2. Improvements with the laboratory data collection and

reporting, laboratory information management systems (LIMS) enhancements and expansions, increased completeness of case data reporting, and improvements with timeliness of reporting are among the prioritized activities for implementation with this funding.

This ICR outlines the requirements for data submission to the U.S. Department of Health and Human Services (HHS) as authorized under this law. In an effort to receive these data in the most efficient manner, the Secretary is requiring that all data be reported through existing public health data reporting methods as described below.

As a guiding principle, data will be sent first to the state or local public health agencies (in accordance with state law or policies) to ensure rapid initiation of case investigations by the state and/or local public health agency. At the same time, laboratory order results will be shared with ordering providers or patients if there is not an ordering provider.

All laboratories, defined as laboratories, non-laboratory testing locations, and other facilities or locations offering point of care testing or in-home testing related to SARS-CoV-2 shall report data for all testing completed, for each individual tested, within 24 hours of result known or determined, on a

daily basis to the appropriate state or local public health agency based on the individual's residence.

Reporting to the state and/or local public health agencies meets the requirement for reporting stated above as this information—under current processes and policies—will then be subsequently provided electronically to the Centers for Disease Control and Prevention (CDC) using an existing pathway and storage location for the data.

For the purposes of this ICR, federal burden is only being placed on fifty states, the District of Columbia, Puerto Rico, US Virgin Islands, and Guam. Authorizing legislation comes from Section 301 of the Public Health Service Act (42 U.S.C. 241). Total estimated burden is 9,720 hours.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
State epidemiologist or informatics staff	CDC-provided CSV file or HL7 messages	54	180	1	9,720
Total					9,720

Jeffrey M. Zirger,

Lead,

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Office of Scientific Integrity,
Office of Science,
Centers for Disease Control and Prevention.

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