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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-20-20HD]

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 Shigella Hypothesis Generating Questionnaire (SHGQ) 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 February 25, 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

Shigella Hypothesis Generating Questionnaire - New - National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Shigella are a family of bacteria that cause the diarrheal disease shigellosis. It is estimated that Shigella causes about 500,000 cases of diarrhea in the United States annually. From 2007 through 2017, there have been 1,046 outbreaks of shigellosis in the United States, with most of these outbreaks attributed to person to person spread. Outbreaks of shigellosis have been reported in a range of settings such as community-wide, daycares, schools, restaurants, and retirement homes. Outbreaks of shigellosis have impacted a range of populations such as children, men who have sex with men, people experiencing homelessness, tight knit religious communities, international travelers, and refugees/displaced persons. Finally, outbreaks of shigellosis have been attributed to a range of transmission modes including person-to-person/no common source, sexual person-to-person contact, contaminated food, and contaminated

water. As part of Shigella outbreak investigations, it is common for state and local health departments to conduct comprehensive interviews with cases and contacts to identify how individuals became sick with shigellosis, to identify individuals who could have come into contact with an individual sick with shigellosis, and to identify strategies to control the cluster or outbreak. As person-to-person contact is the most common mode of transmission for shigellosis, and shigellosis is highly contagious, it can be challenging to identify how individuals could have become ill. As a result, comprehensive hypothesis generating questionnaires focused on a range of settings, activities, and potential modes of transmission are needed to guide prevention and control activities.

There is currently no national, standardized hypothesis generating interview data collection instrument for use during single or multistate shigellosis cluster or outbreak investigations. More detailed data about shigellosis cases involved in single or multistate clusters or outbreaks are needed to better characterize the epidemiology of clusters and outbreaks and to identify modes or settings of importance by collecting the following information. This information will not only help inform routine cluster and outbreak investigation activities but also guide awareness efforts and appropriate

prevention strategies. To meet these needs the Shigella Hypothesis Generating Questionnaire (SHGQ) was developed.

The SHGQ will be administered by state and local public health officials via telephone interviews with cases of shigellosis or their proxy who are part of a shigellosis cluster or outbreak. The SHGQ will collect information on demographics characteristics, household information and family member event and activity attendance, clinical signs and symptoms, medical care and treatment information, travel history, contact with international travelers or other ill individuals, event and activity attendance, limited food and water exposure, work, visit, and volunteer locations, childcare and school attendance, and recent sexual partner(s) and activity.

This interview activity is consistent with the state's existing authority to investigate reports of notifiable diseases for routine surveillance purposes; therefore, formal consent to participate in the activity is not required. However, cases may choose not to participate and may choose not to answer any question they do not wish to answer. It will take health department personnel approximately 45 minutes to administer the questionnaire to an estimated 1500 patient respondents. This results in an estimated annual burden to the public of 1,125 hours.

Estimated Annualized Burden Hours

| Type of Respondents | Form Name | Number of Respondents | Number of Responses per Respondent | Average Burden per Response (in hours) |
|--|--|-----------------------|------------------------------------|--|
| Shigellosis case patients identified as part of outbreak or cluster investigations | Shigella Hypothesis Generating Questionnaire | 1500 | 1 | 45/60 |

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