



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-19-19LI; Docket No. CDC-2018-0120]

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 Long-term sequela of Rocky Mountain spotted fever (RMSF). This project will look back at hospitalized cases of RMSF to see if they fully recovered from their illness, or if they still experience long-term neurological effects potentially tied to their RMSF episode.

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

ADDRESSES: You may submit comments, identified by Docket No. CDC-2018-0120 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 CONTACT: 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

Long-term sequela of Rocky Mountain spotted fever (RMSF) - New ICR - National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Data collection for this investigation was initiated in July 2018 following OMB approval on 7/22/2018, with a second approval on 11/15/2018 under the Emergency Epidemic Investigations (EEI) Generic ICR (OMB Control Number 0920-1011, exp 1/31/2020). A full OMB package is being submitted to allow for continuation of the project.

Rocky Mountain spotted fever (RMSF), a life-threatening and rapidly progressive tickborne disease, is caused by infection with the bacterium *Rickettsia rickettsii*. Infection begins with non-specific symptoms like fever, headache, and muscle pain, but when left untreated the bacteria can cause damage to blood vessels throughout the body leading to organ and tissue damage. Delay in recognition and treatment of RMSF can result in

irreparable damage leading to amputation of extremities, neurological deficits (such as hearing loss, paralysis, and encephalopathy), and death.

Case series in the peer-reviewed literature document long term sequelae (LTS) from RMSF in anywhere from 3-55% of cases, yet characterization of the long-term impacts is still not well understood, and only a handful of studies have examined them in detail. Results of neurologic damage caused during acute RMSF illness may include symptoms ranging from paresthesia, insomnia and behavioral concerns to loss of hearing, motor or language dysfunction, and chronic pain.

This study will gather information related to neurologic sequela following RMSF illness. Information for this study will come from three sources: medical charts, patient interviews, and neurological exams with a cognitive/developmental assessment for children. Resulting data will provide information to healthcare providers, patients, and policy makers about the long term consequences of severe RMSF, including time to recovery, self-reported impact to daily function, and will look to identify risk factors during acute illness which may be associated with long term impairment.

There is no cost to respondents other than the time to participate. Total estimated burden is 126 hours. Authorizing

Legislation comes from Section 301 of the Public Health Service Act (42 U.S.C. 241).

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) |
|---------------------|---------------------------------|-----------------------|------------------------------------|--|-------------------------|
| General Public | Patient screening questionnaire | 250 | 1 | 10/60 | 42 |
| | Neurological exam form | 125 | 1 | 40/60 | 84 |
| Total | | | | | 126 |

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[FR Doc. 2019-01333 Filed: 2/6/2019 8:45 am; Publication Date: 2/7/2019]