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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–19–0009; Docket No. CDC–2019–0014]

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 ''National Disease Surveillance Program—I. Case Reports'' to collect disease-specific surveillance reports of four rare, uncommon, or infrequent diseases.

DATES: CDC must receive written comments on or before June 7, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0014 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 NE, 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 NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *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

National Disease Surveillance Program—I. Case Reports—Revision—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Surveillance of the incidence and distribution of disease has been an important function of the US Public Health Service (PHS) since an 1878 Act of Congress authorized the PHS to collect morbidity reports. After the Malaria Control in War Areas Program had fulfilled its original 1942 objective of reducing malaria transmission, its basic tenets were carried forward and broadened by the formation of the Communicable Disease Center (CDC) in 1946. CDC was conceived of as a well-equipped, broadly staffed agency used to translate facts about analysis of morbidity and mortality statistics on communicable diseases and through field investigations.

It was soon recognized that control measures (such as the DDT spraying for malaria) did not alleviate the threat of disease reintroduction. In 1950, the Malaria Surveillance Program began and in 1952, the National Surveillance Program started. Both programs were based on the premise that diseases cannot be diagnosed, prevented, or controlled until existing knowledge is expanded and new ideas developed and implemented. The original scope of the National Surveillance Program included the study of malaria, murine typhus, smallpox, psittacosis, diphtheria, leprosy, and sylvatic plague. Over the years, the mandate of CDC has broadened in preventive health activities and the surveillance systems maintained have expanded. This program is authorized under the Public Health Service Act, Section 301 and 306 (42 U.S.C. 241 and 242K).

This ICR covers surveillance activities for these four, rare diseases:

1. Creutzfeldt-Jakob Disease (CJD)
2. Reye Syndrome
3. Kawasaki syndrome
4. Acute Flaccid Myelitis

Changes are being requested only to the Kawasaki Syndrome form. The CDC KD form has been used as part of a passive national surveillance system to collect additional case information, including data on cardiac complications and treatment. In recent years, new treatments and/or treatment combinations have been implemented at some institutions; this information is not collected on the current form. Also, more specific information regarding the results of coronary artery testing would be beneficial for assessing disease severity and treatment effectiveness. To incorporate these additions to the form without increasing the estimated burden, some current questions on the form, specifically those collecting information on the presence or absence of certain complications, will be removed. The form will be targeted to sentinel KD research centers across the US, reducing the number of respondents compared to previous years.

Annual burden is estimated to decrease by 53 hours since the last approval (June, 2019). There is no cost

to respondents other than the time to participate.

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)
Epidemiologists	CJD	10	2	20/60	7
	Kawasaki Syndrome	25	10	15/60	63
	Reye Syndrome	50	1	20/60	17
	Acute Flaccid Myelitis	100	1	30/60	50
Total					137

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2019–0029; NIOSH–327]

Mesothelioma Registry Feasibility; Request for Information

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Request for information.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH), within the Centers for Disease Control and Prevention (CDC), announces the opening of a docket to obtain information on the feasibility of a registry designed to track mesothelioma cases in the United States, as well as recommendations on enrollment, data collection, confidentiality, and registry maintenance. The purpose of such a registry would be to collect information that could be used to develop and improve standards of care and to identify gaps in mesothelioma prevention and treatment.

DATES: Comments must be received by July 8, 2019.

ADDRESSES: Comments may be submitted electronically, through the Federal eRulemaking Portal: *http://www.regulations.gov,* or by sending a hard copy to the NIOSH Docket Office, Robert A. Taft Laboratories, MS–C34, 1090 Tusculum Avenue, Cincinnati, OH 45226. All written submissions received must include the agency name (Centers for Disease Control and Prevention, HHS) and docket number (CDC–2019–0029; NIOSH–327) for this action. All relevant comments, including any personal information provided, will be posted without change to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Rachel Weiss, Program Analyst, 1090 Tusculum Avenue, MS: C–48, Cincinnati, OH 45226; telephone (855) 818–1629 (this is a toll-free number); email *NIOSHregs@cdc.gov.*

SUPPLEMENTARY INFORMATION: The fiscal year 2019 appropriations act charged NIOSH with initiating a feasibility study for a National Mesothelioma Registry.[1] Mesothelioma is a rare cancer of the body's lining tissue, most commonly the lining of the chest and lungs (pleura) and the lining of the abdomen (peritoneum). The most common risk factor for mesothelioma is prior asbestos exposure. Mesothelioma treatments are limited and survival is generally poor. NIOSH is the Federal agency that develops new knowledge in the field of occupational safety and health and transfers that knowledge into practice. NIOSH has a strong interest in preventing mesothelioma and helping people with the disease, since the most common known cause is exposure to asbestos, a dangerous occupational hazard for many workers.

Cancer is a reportable disease in every state. Data about new cases of mesothelioma are reported to state or local cancer registries, annually submitted to CDC or the National Cancer Institute (NCI), and then compiled by CDC in the U.S. Cancer Statistics database.[2] However, existing cancer registries collect only limited information about potential risk factors and issues occurring over time, such as treatment complications. In addition to the limitations on the scope of existing surveillance systems, it may take 6 months or more from the time of diagnosis until mesothelioma cases are initially reported to a cancer registry, and then another 1–2 years to be reported in U.S. Cancer Statistics. Because about half of those diagnosed with mesothelioma die within 1 year, to be of benefit to registrants, a registry would need to develop a case-finding methodology to enroll registrants as soon as possible after diagnosis to allow timely access to contemporary state-of-the-art therapy and clinical trials. It has been reported that many mesothelioma patients do not receive this level of care.[3] Ideally, the case-finding methodology would be national in scope and identify most people diagnosed with mesothelioma, thus allowing researchers to use this current data to determine incidence and prevalence, demographics, and risk factors, as required by the 2019 appropriations act. A National Mesothelioma Registry could address the limitations of existing registries by reducing case reporting delays, collecting detailed information regarding risk and prognostic factors, and by engaging with researchers to better enable them to identify gaps in the current understanding of mesothelioma prevention and treatment and improve the standard of care for current and future patients.

In order to study the feasibility of establishing a National Mesothelioma Registry, NIOSH requests information

[1] *Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019,* HR 6157 (enacted). *See also Department Of Defense for the Fiscal Year Ending September 30, 2019, and for Other Purposes,* House of Representatives Conference Report No. 115–952 (2018). The conference report accompanies HR 6157 and explicitly directs NIOSH to ''initiate a feasibility study for a patient registry, which would include developing case finding methodology to determine incidence and prevalence, demographics, and risk factors.''

[2] U.S. Cancer Statistics: the Official Federal Cancer Statistics. *https://www.cdc.gov/cancer/uscs/index.htm.*

[3] Waller DA [2018], *The Management of Malignant Pleural Mesothelioma in the USA 2004–13—A Decade of Lost Opportunity?* J Thorac Dis 10(Suppl 9):S1044–S1046.