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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.