

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

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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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](mailto:NIOSHregs@cdc.gov).

SUPPLEMENTARY INFORMATION: The fiscal year 2019 appropriations act charged NIOSH with initiating a feasibility study for a National Mesothelioma Registry.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup> 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

<sup>1</sup> 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."

<sup>2</sup> U.S. Cancer Statistics: the Official Federal Cancer Statistics. <https://www.cdc.gov/cancer/uscs/index.htm>.

<sup>3</sup> 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.

from the public on the potential usefulness of a registry and potential approaches to establishing and operating it. Accordingly, NIOSH seeks input and advice from all interested parties in response to the following questions:

1. Would a registry be an effective tool in improving mesothelioma patient care? If yes, please describe how a registry could be used to improve current care.

2. Would a registry be an effective tool in facilitating clinical mesothelioma research? If yes, please describe how a registry could be used to facilitate clinical mesothelioma research.

3. Would a registry be an effective tool in facilitating basic or epidemiological mesothelioma research? If yes, please describe how a registry could be used to facilitate basic or epidemiological research.

4. What are the best potential approaches to recruiting and enrolling mesothelioma patients in a registry as soon as possible after diagnosis? What barriers can be anticipated? How can these barriers be overcome?

5. What information should be collected by a mesothelioma registry? How would that information be useful for improving patient care or facilitating clinical, basic, or epidemiological research?

6. What services should a registry provide to mesothelioma patients, clinicians, researchers, and other interested stakeholders?

7. Who should have access to information gathered by a mesothelioma registry?

8. How could a mesothelioma registry protect the confidentiality of information about registry participants yet still be used for patient care and research? Please describe how personally identifiable information should be protected.

9. Are there particular types of organizations that would be best suited to host or manage a National Mesothelioma Registry? If so, please explain the advantages and disadvantages of the recommended types of organizations.

10. What types of resources would be needed to establish and maintain or participate in a National Mesothelioma Registry, including for clinical sites that diagnose patients, cancer registries and state public health departments, a central data center, and potentially other participants involved in recruiting and enrolling patients, gathering and storing information, providing various services, and following patients over time?

11. Is there other information that NIOSH should consider in assessing the potential usefulness, feasibility, and potential approaches to establishing and operating a National Mesothelioma Registry? If yes, please describe.

Dated: April 2, 2019.

**Frank J. Hearl,**

*Chief of Staff, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier CMS-R-64 and CMS-10699]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by June 7, 2019.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number \_\_\_\_\_, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** William N. Parham at (410) 786-4669.

#### SUPPLEMENTARY INFORMATION:

##### Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-R-64 Indirect Medical Education and Direct Graduate Medical Education

CMS-10699 Information Collection Requirements Associated with Drug Pricing Transparency and Supporting Regulations in 42 CFR 403.1202

Under the 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. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before