

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–19–19AEG; Docket No. CDC–2019–0025]

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 Verona Integron-Encoded Metallo-β-Lactamase (VIM)-Producing Carbapenem-Resistant *Pseudomonas aeruginosa* Infections Associated with Invasive Medical Procedures in Tijuana, Mexico. This project is being developed to identify infections among individuals in the U.S. who had surgery at Facility 1 in Tijuana, Mexico in order to prevent the spread of resistance in the U.S.

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

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0025 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

Verona Integron-Encoded Metallo-β-Lactamase (VIM)-Producing Carbapenem-Resistant *Pseudomonas aeruginosa* Infections Associated with Invasive Medical Procedures in Tijuana, Mexico—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is investigating an outbreak of highly resistant *Pseudomonas aeruginosa* infections associated with bariatric surgery at a hospital in Tijuana, Mexico. Approximately 750 Americans from 45 states have had surgery at this facility since August 1, 2018. Among these individuals, approximately 200 had surgery since January 1, 2019, and are still at risk for developing infection and/or having infections that are still being treated in the U.S. healthcare system. CDC recently received the contact information for these exposed individuals to enable public health response. To help prevent spread of this resistant organism in U.S. hospitals, and to ensure that individuals who develop infection get prompt and appropriate treatment, a public health response was initiated to contact individuals exposed to Facility 1 in order to assess whether they developed infections and whether they have been hospitalized since their surgery in Mexico.

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)
Individuals exposed for Facility 1 since January 1, 2019.	Verona Integron-Encoded Metallo-β-Lactamase (VIM)-Producing Carbapenem-Resistant <i>Pseudomonas aeruginosa</i> Infections Associated with Invasive Medical Procedures in Tijuana, Mexico: Survey.	197	1	20/60	66
Total	66

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

[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