

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–20–20DV; Docket No. CDC–2019–0114]

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 “Chronic Q Fever in the United States: Enhanced Clinical Surveillance.” This enhanced medical surveillance for chronic Q fever will collect specific clinical data not otherwise collected during routine public health surveillance to allow for better characterization of the clinical presentation and risk factors of chronic Q fever in the United States.

DATES: CDC must receive written comments on or before February 21, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0114 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 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, of the 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

Chronic Q Fever in the United States: Enhanced Clinical Surveillance—New—National Center for Emerging Zoonotic and Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Q fever is a worldwide zoonosis caused by *Coxiella burnetii* with acute and chronic disease presentations. Chronic Q fever can manifest months to years after the primary infection and is rare, occurring in <5% of persons with an acute infection. Chronic Q fever can take on several clinical forms, including endocarditis, chronic hepatitis, chronic vascular infections, osteomyelitis, and osteoarthritis. In the United States, Q fever cases are reported via the National Notifiable Disease Surveillance System; however, limited information is collected on the various clinical manifestation of chronic Q fever or patients pre-existing risk factors. Data on outcomes other than death or hospitalizations are not collected by the current surveillance.

Because of this lack of data, the true burden and proportion of cases exhibiting endocarditis and other forms of chronic Q fever in the United States is unknown. We plan to establish an enhanced medical surveillance for chronic Q fever by working with consulting clinicians to gather additional and more specific clinical data not otherwise collected during routine public health surveillance for chronic Q fever. This information will allow for better characterization of the clinical presentation and risk factors of chronic Q fever in the United States. The results will help characterize an under-recognized disease and provide valuable data to educate physicians on identifying and diagnosing these cases. CDC is requesting approval for five burden hours annually. There is no cost to respondents other than their time.

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)
Physician	Chronic Q fever enhanced surveillance report form.	15	1	20/60	5
Total	5

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-20-20DC; Docket No. CDC-2019-0113]

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 “2019 Lung Injury Response Understanding Vaping Practices In the United States.” This is a formative study to identify why people are getting sick after vaping/dabbing, in order to narrow the list of products, substances, and risk factors requiring further public health action.

DATES: CDC must receive written comments on or before February 21, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2019-0113 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 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 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

2019 Lung Injury Response Understanding Vaping Practices In the United States—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC), National Center for Injury Prevention and Control (NCIPC)

requests approval for a New Information Collection, “2019 Lung Injury Response Understanding Vaping Practices In the United States.”

In early August 2019, initial cases of e-cigarette, or vaping, product use associated lung injury (EVALI) were reported to CDC. As of November 13, 2019, 2,172 EVALI cases have been reported to CDC from 49 states, the District of Columbia, the US Virgin Islands, and Puerto Rico; 42 deaths have been reported among these cases. A multi-state centrally coordinated response for this severe pulmonary injury was established at CDC to assist each state/local/territory jurisdiction in making rapid, practical decisions for actions to prevent and control this public health problem.

To date, all EVALI patients have reported a history of using e-cigarette, or vaping, products. The latest national and state findings suggest products containing THC, particularly from informal sources like friends, or family, or in-person or online dealers, are linked to most of the cases and play a major role in the outbreak. In addition, vitamin E has been identified as a chemical of concern among people with e-cigarette, or vaping, product use associated lung injury (EVALI). However, while it appears that vitamin E acetate is associated with EVALI, evidence is not yet sufficient to rule out contribution of other chemicals of concern to EVALI. Many different substances and product sources are still under investigation, and it may be that there is more than one cause of this outbreak. At present, there is very little data on which to compare EVALI cases to individuals who are vaping the same products at the same frequency but have not developed EVALI. Comparing EVALI cases to people who vape but have not developed EVALI in a timely way is very important for narrowing the list of products, substances, and risk factors requiring further public health action (e.g., continuing to refine communication messages) and additional studies (e.g., prioritizing samples for laboratory testing). Further, there is insufficient data for guiding the selection of controls for a rigorous case control study (lack of uniformity in demographic characteristics and product brands and types).

The data collected will be used to identify product types, “brands”, devices, and frequency of use (collectively referred to as use characteristics) from a geographically diverse convenience sample of individuals who report vaping THC but have not developed EVALI. These data will enable CDC to compare the